

Mechanical Analysis of Explanted Saline-filled Breast Implants Exposed to Betadine Pocket Irrigation

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Background: Because of concerns that exposure to povidone-iodine (Betadine) may lead to early breast implant failure, the Food and Drug Administration announced in 2000 that any contact between implants and Betadine is contraindicated. The evidence cited by the Food and Drug Administration primarily referred to Betadine added to saline implant filler solution and not to povidone-iodine used for pocket irrigation.

Objective: Thirteen explanted Mentor saline solution-filled devices that had been exposed to Betadine pocket irrigation during implantation were studied for any loss of implant shell integrity.

Methods: The 13 explants had been in place 1 week to 55 months, and none had intraluminal Betadine exposure. Twelve of the 13 explants were intact when removed, and one had leaked through the anterior valve. All were examined for any signs of patch-shell delamination. The mechanical properties of tensile strength, percent elongation, force-to-break, tear resistance, and patch bond strength were also measured.

Results: No shell delamination or disruption of the sealing patch bond was found in any of the 13 explants placed in Betadine-irrigated pockets. In addition, the measured mechanical properties of the explants exceeded American Society for Testing and Materials requirements, with the exception of the textured explants ($n = 2$), which failed to meet the minimum elongation standards.

Conclusions: We found no evidence of patch or shell delamination in Mentor implants that had extraluminal contact with Betadine irrigation and were later explanted. We believe that the lower mechanical properties of the two textured implants are probably related to the texturing process rather than to Betadine pocket irritation. (*Aesthetic Surg J* 2002;22:438-445.)

For decades, plastic surgeons have used diluted povidone-iodine as an antiseptic pocket irrigant during breast augmentation and reconstruction with silicone gel- and saline-filled implants. This practice gained acceptance because of growing suspicion that microorganisms might play a role in the development of severe capsular contracture, which has historically been a major local complication of breast implantation. Although other antimicrobial agents have been used for irrigation, most are not as effective as povidone-iodine solution (Betadine; Purdue Frederick, Stamford, CT) against a broad spectrum of the gram-positive and gram-negative organisms most commonly cultured from breast implant and periprosthetic capsule surfaces. Years of clinical experience with Betadine pocket irrigation suggested no adverse events or any increased frequency of device failures associated with its use. Nevertheless, in 2000, the Food and Drug Administration (FDA) reported that any contact between Betadine and breast

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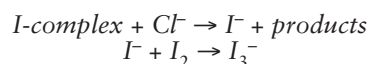
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implants was contraindicated. The FDA ordered that implant product labels and patient information materials contain warnings against Betadine contact.

The FDA's pronouncement was based on results of clinical trials that were part of the premarket approval applications for saline-filled breast implants manufactured by Mentor Corporation (Santa Barbara, CA) and McGhan Medical (Santa Barbara, CA). On the basis of adverse event reports, Mentor noticed a 3-fold increase in implant deflations when Betadine was added to the intraluminal saline solution filler. The device failures typically occurred at the patch-shell interface, which suggested that Betadine might adversely affect the adhesive joint between the patch and the shell.

Concerned that Betadine might somehow compromise the integrity of saline-filled breast implant shells, Mentor conducted in vitro experiments with Betadine used as a portion of the implant filler or as an immersion media. Smooth and textured implants were filled with a 10% Betadine/90% normal saline solution or 20% Betadine/80% normal saline solution and immersed in saline solution for 7 weeks to 4 months.¹ All devices with Betadine added to the filler solution experienced delamination of the shell or other components. However, when implants were filled with normal saline solution and immersed in 100% Betadine for a week, none of the devices showed signs of delamination or physical properties changes. These experiments suggested that exposure of the outer surface of a breast implant shell to Betadine poses no problem, whereas intraluminal Betadine somehow damages the shell. Even though Mentor found no correlation between Betadine used as a pocket irrigant and shell degradation, the FDA decided that Betadine use during implantation should be avoided.

An interaction between Betadine and saline solution may generate an environment that degrades the adhesive joint between the implant patch and shell. The primary active component of Betadine is iodine, a powerful oxidant. The precise effect of iodine (I_2) in saline solution (NaCl) is unknown. However, a reaction between the chloride ion in the saline solution and the molecular iodine in Betadine may produce a small amount of iodide ion, which could, in turn, react with molecular iodine to generate I_3^- . These reactions may be summarized as follows:



HI_3 is known to be a strong catalyst for the polymerization of octamethylcyclotetrasiloxane (sometimes referred to as D_4) to polydimethylsiloxane.² Hence, one would expect any form of I_3^- to be an equally good catalyst for the degradation of a polydimethylsiloxane-based adhesive.

To investigate the issue of breast implant exposure to Betadine, we measured the mechanical properties of 13 explanted Mentor saline-filled implants that had been inserted into pockets irrigated with Betadine during implantation surgery. None of these implants had intraluminal Betadine contact. Specifically, we looked for any signs of patch-shell delamination.

Methods

After the FDA issued its directive against use of Betadine in breast implantation, one of the authors (V.L.Y.) began collecting saline-filled implants that had been exposed to Betadine pocket irrigation and later consecutively explanted. Standard, full-strength Betadine solution (povidone-iodine 10%) had been used. Because the same surgeon had originally placed the implants, the precise durations of implantation were known, and Betadine pocket irrigation could be confirmed in the operative reports. It was also certain that no Betadine had been added to the implant filler solution. Within a few months, 13 explants manufactured by Mentor were identified and collected, then sent to the Center for Implant Retrieval and Analysis at Washington University in St. Louis, which is supported by a research group that has tested implants since 1992 and has developed well-established protocols for material properties analyses.

Our testing methods and equipment have been previously described.³⁻⁵ In short, we used an Instron 5583 (Instron Corp., Canton, MA) equipped with a video extensometer to measure the mechanical properties of multiple specimens cut from each tested implant's elastomer shell. Whenever possible, we follow American Society for Testing and Materials (ASTM) testing protocols. The specific variables examined in this study were as follows: tensile strength, percent elongation, and force-to-break (ASTM D 412); tear resistance (ASTM D 624); and patch bond strength (ASTM F 703). To measure the force-to-break and percent elongation variables, the ends of the tensile testing specimens were placed in the Instron's pneumatic grips and pulled apart at a steady displacement rate of 10 in/min until the specimen

Table 1. Mentor implants tested after pocket irrigation with Betadine and subsequent explanation*

Implantation time (mo)	Fill volume (cc)	Surface type	Explant status	Reason for explantation
0.2	525	Smooth	Intact	Left periprosthetic infection /both implants removed at request of patient
0.2	525	Smooth	Intact	
1.0	775	Smooth	Intact	Size change requested (smaller)
4.4	325	Smooth	Intact	Size asymmetry
16.0	300	Smooth	Intact	Size change requested (smaller)
16.0	300	Smooth	Intact	
20.0	350	Smooth	Intact	Malpositioned pocket
30.5	350	Smooth	Intact	Patient decided she preferred appearance without implants
30.5	350	Smooth	Intact	
47.0	300	Smooth	Intact	Size change requested (larger)
47.0	300	Smooth	Intact	
55.0	425	Textured	Deflated	Left implant deflation
55.0	425	Textured	Intact	

*Lines separate different patients.

broke. These data were then converted to engineering stress versus engineering strain curves.

For each explant, 5 ASTM D 412 Die C half-scale specimens were used for testing tensile strength, 3 ASTM D 624 Die C half-scale specimens for tear resistance, and 3 ASTM D 703 specimens for patch bond adherence. The tensile and tear specimens were obtained from the anterior surface of the shell. ASTM F 703 state that the breaking force in tension shall be no less than 2.5 pounds (11.12 N) and the percent elongation shall be 350% minimum when tested in accordance with ASTM D 412 methods. This standard specifies that Die C shall be used to prepare the specimens. However, our validated testing protocol uses a half-scale Die C because of the limited implant shell material available. Preliminary tests on 20 saline implant control shells determined that results obtained with Die C and with Die C half-scale were related. The ratios of the Die C to the Die C half-scale values for elongation and breaking force were 1.03 and 1.75 respectively. These values were applied to the present Die C half-scale results to obtain the breaking force and elongation measurements for comparison with ASTM standard specifications.

In our implant studies, we typically compare measurements from explanted implants to lot-matched controls or to the measured properties ranges (maximum to minimum) of controls for particular implant models. For the 13 Mentor explants tested in this study, we did not have either lot-matched controls or control range data. Thus

we could compare their mechanical properties only to ASTM requirements for breast implant shells.

Results

Basic details about the 13 Mentor explants tested in this study are shown in Table 1, which gives implantation times, implant fill volume, integrity status at time of removal, and reason for explantation. The 13 devices were removed from 8 patients who had undergone breast augmentation, of whom 5 underwent bilateral explantations and 3 underwent unilateral explantations. The mean duration of implantation was 24.8 months (range 0.2 to 55 months). All the explants were round, 11 had a smooth surface, and 12 were placed in the submuscular plane; 1 was a replacement implant inserted in a preexisting subglandular pocket. All implants were filled with standard sterile Sodium Chloride U.S.P. Solution for Injection, implanted by the same surgeon who removed them, and placed in pockets that had been irrigated with standard, full strength Betadine solution (povidone-iodine 10%).

One of the implants with the longest time in vivo (55 months) began to deflate approximately 1 year before it was removed, but the patient delayed implant exchange. When explanted this implant seemed to be leaking through the anterior diaphragm valve. The shell and posterior patch looked no different than the patient's contralateral textured implant. Specifically, the patch-shell interface was not disrupted, and there was no sign of

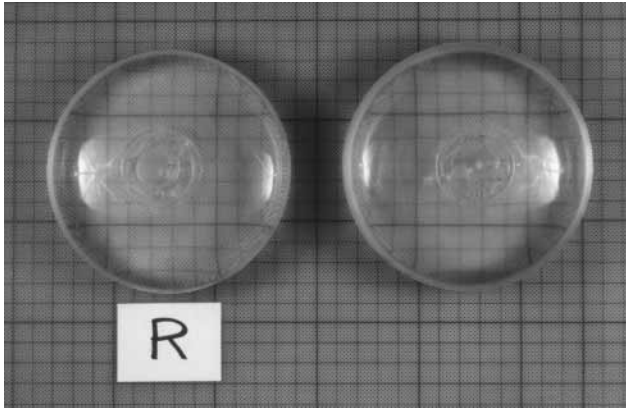


Figure 1. Photograph of the posterior surface of a patient's cleaned right explant (R) removed after 16 months in vivo. The explant exposed to Betadine pocket irrigation (left) looks no different from an unimplanted control (right).



Figure 2. Closer view of the posterior patch region of a shell exposed to Betadine pocket irrigation and removed after 16 months. The photograph reveals no signs of patch delamination or disruption at the patch-shell interface.

shell or patch delamination. A detailed failure analysis of this explant was not performed, but we presume this one deflation resulted from a valve failure.

In spite of the use of Betadine, 1 implant had to be removed 6 days after implantation because of a presumed periprosthetic infection, indicated by unusual breast tenderness and a fever of 102° F. On explantation the breast pocket was filled with turbid fluid but no suppuration. When the fluid was cultured, no organism growth was

seen; however, the patient had been taking antibiotics since surgery. She requested bilateral explantation until the infection resolved and underwent reimplantation approximately 2.5 months later, with no complications.

Figure 1 is a 35-mm photograph of the posterior surface of one of the tested explants after it had been cleaned, lying next to a control (never implanted) of the same type and similar volume. The explanted implant had been placed in a pocket irrigated with Betadine and remained in vivo for 16 months, when it was removed intact. There were no observable differences between the explant and control. A magnified view of the patch region of the other explant with a 16-month implantation time is seen in Figure 2. Neither of these photographed explants had visible signs of delamination, disruption at the patch-shell interface, or discoloration. Similar observations were made for the other explants analyzed in this study.

As stated earlier, we could not compare the mechanical properties measurements of the explants to lot-matched controls and therefore cannot comment on whether the shells exposed to Betadine pocket irrigation underwent any specific changes in their strength characteristics. Instead, we qualitatively assessed the mechanical properties of the explant shells, which are presented independent of control data.

Figure 3 presents the estimation of force-to-break data, shown according to implantation time, for the 13 Mentor explant shells that were placed in pockets irrigated with Betadine. This bar graph, which represents the average of the tested specimens from each explant, shows how many pounds of force the elastomer withstood before the specimen ruptured. All explant shells exceeded ASTM requirements of 2.5 pounds (p) for elastomer strength. Additional tensile specimens were cut from the textured shells using Die C full-scale and tested at 20 in/min to check the scaling parameters from the half-scale to full-scale die. The scaling parameters for elongation and force-to-break were determined to be very close to the values obtained in our preliminary tests on control shells. We also found that the shell thickness of a textured implant varies considerably. Furthermore, the thickness of the anterior surface is generally much thinner than the posterior surface. For both textured explant shells, the force-to-break at the thinner shell regions was less than 2.5 pounds, but the average for both the intact and deflated shells exceeded the ASTM specification.

Whereas *force-to-break* relates to the largest sustainable force the elastomer can tolerate, *elongation* refers to the longest enduring stretching deformation the specimen can withstand before rupturing. According to ASTM, the elastomer used in breast implant shells should be able to elongate 350% before the test specimen breaks. The average percent (%) elongation for the 5 specimens tested from the 13 Mentor shells exposed to extraluminal Betadine is shown in Figure 4. All tested smooth implant shells surpassed the ASTM requirement, but both textured shells were below the minimum requirement, with measurements of 233% and 245%. The average elongation values for the textured devices include both the Die C half-scale and full-scale measurements.

Tear resistance was determined by testing 3 specimens from each explant to measure the force per unit thickness required to tear the elastomer as the specimen is pulled in the Instron grips at a constant rate. The tear resistance—expressed in pounds per inch—is calculated as the amount of force applied divided by a specimen’s thickness. Figure 5 presents the average of the 3 specimens tested from each explanted Mentor shell. No ASTM requirement exists for this variable, but our data indicate that the 11 smooth shells withstood a range of 60 to 75 pounds of force per inch before tearing. The 2 textured shells tore when only 34 and 38 pounds of force per inch were applied.

We found no shell delamination or disruption of the sealing patch bond in any of the 13 Mentor explants that had been placed in pockets irrigated with Betadine. Patch bond strength measurements were obtained by testing 3 specimens from each shell, with the patch–shell interface centered in the cut specimens. This is a pass/fail test. As shown in Table 2, all 13 patches passed the ASTM test.

Discussion

In adverse event reports from the late 1990s, Mentor detected an association between early device failure and the addition of Betadine to the saline solution used to fill its breast implants. Mentor’s data analysis from its clinical trials conducted as part of their premarket approval application for saline-filled implants also found a correlation between failed devices and Betadine used as an “intraoperative medication.” However, because of the way the reporting form was designed, Mentor had no way of knowing whether the Betadine was used for pocket irrigation or as part of the implant filler.¹

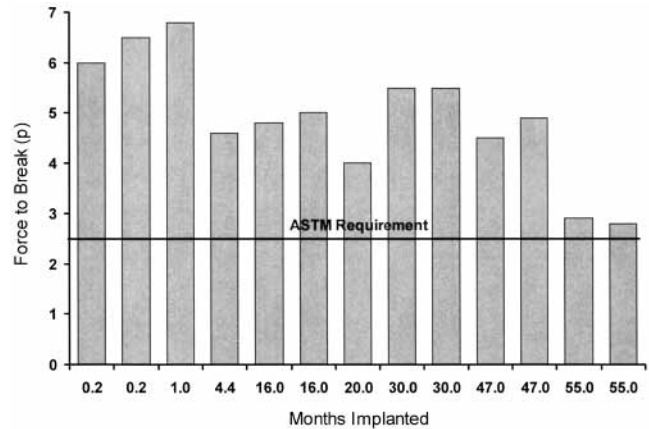


Figure 3. Force-at-break data plotted according to implantation time for the 13 Mentor explant shells subjected to Betadine pocket irrigation. P indicates how many pounds of force were applied to test specimens before the elastomer ruptured.

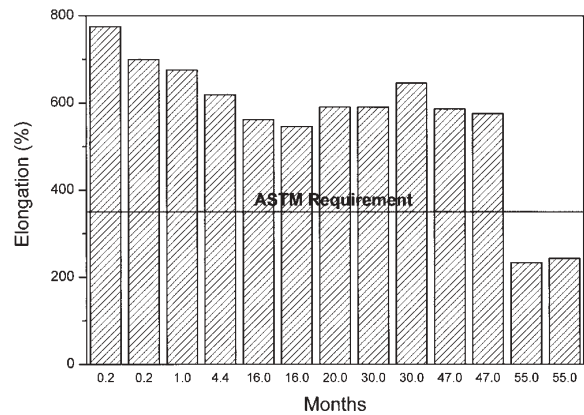


Figure 4. Percent elongation before break of the 13 explant shells exposed to Betadine pocket irrigation shown according to implantation time. All smooth-surface shells exceed the ASTM requirement of 350%, but neither of the textured shells meet the minimum standard.

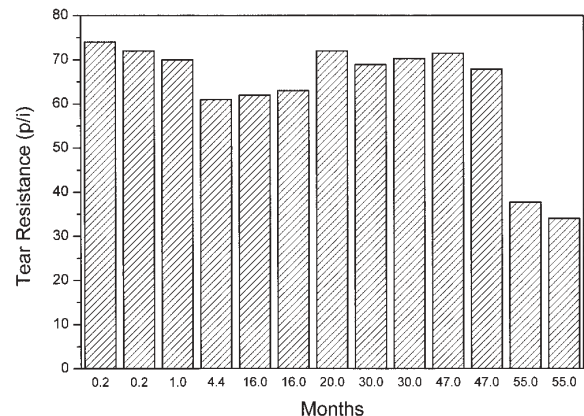


Figure 5. Tear resistance versus implantation time for the 13 explant shells implanted with Betadine pocket irrigation. The smooth shells withstood between 60 to 75 pounds of force per inch (p/i) before tearing. The 2 textured shells withstood less than 40 p/i.

Table 2. Patch bond adherence of Mentor implants tested after pocket irrigation with Betadine and subsequent explantation

Implantation time (mos)	Patch bond adherence
0.2	Passed ASTM test
0.2	Passed ASTM test
1.0	Passed ASTM test
4.4	Passed ASTM test
16.0	Passed ASTM test
16.0	Passed ASTM test
20.0	Passed ASTM test
30.5	Passed ASTM test
30.5	Passed ASTM test
47.0	Passed ASTM test
47.0	Passed ASTM test
55.0	Passed ASTM test
55.0	Passed ASTM test

Additional in vitro tests determined that Betadine added to the saline solution filler does indeed cause delamination of the shell. However, implants filled with saline solution only and soaked in Betadine for 1 week demonstrated no signs of delamination. The study presented here tested explanted Mentor devices that had been placed in Betadine-irrigated pockets (extraluminal exposure) and removed after 1 week to 55 months. None of these explants showed any indications of patch or shell delamination. Furthermore, all the smooth-surface implants had mechanical properties that exceeded ASTM requirements. However, neither of the 2 textured implants met the minimum standards.

We do not know why the mechanical properties of the 2 Mentor Siltex (textured) implants tested in this study were significantly lower than those of the 11 smooth-surfaced implants. However, we doubt that the difference is related to the use of Betadine pocket irrigation, because none of the explanted shells had delaminated or separated at the patch interface. A more plausible possibility is that the texturing process affects the mechanical properties of the shell. At the July 9, 2002, public advisory committee meeting of the FDA's General and Plastic Surgery Devices Panel, Mentor presented data from its failure analysis of explants returned to the company after their removal. Although few details were given, Mentor noted that failure caused by material separation (an irregularly-patterned separation in the shell material) occurred more often in Siltex implants than in

smooth devices.⁶ Testing of retrieved implants suggested that this type of failure is caused by an acute or tight fold in the shell that produces high stress.

Since the FDA's directive to stop the use of Betadine with breast implants, one other research team has examined the issue from a limited material properties perspective. Becker and Becker⁷ concluded that Betadine weakens the silicone tubing of adjustable implants (tissue expanders). Pieces of fill tubing from nonimplanted and explanted expanders were soaked in either Betadine or saline solution for 2 weeks and then tested for breaking strength with a tensiometer. The tubes soaked in Betadine had significantly lower breaking strengths than the tubing soaked in saline solution or removed from patients. It is important to note that silicone tubing undergoes a different vulcanization process than the silicone elastomer used to make saline-filled breast implant shells. For example, many fill tubes are heat cured with a peroxide catalyst, whereas the elastomer used for saline-filled implant shells are vulcanized at room temperature. This difference in vulcanization processes may cause a significant change in the long-term durability of fill tubes placed in a Betadine environment.

With respect to the antimicrobial value of Betadine, 2 controlled studies of capsular contracture formation and the use of 5% povidone-iodine for perioperative pocket irrigation have been conducted by Burkhardt et al.^{8,9} In these prospective and blinded investigations of Mentor and McGhan saline-filled implants, patients received a textured implant on one side and a smooth one on the other; in addition, one breast pocket of each patient was irrigated with Betadine and the other with saline solution. The results were inconclusive; Betadine irrigation had no effect on contracture grade in a study of Mentor Siltex saline-filled implants,⁸ but a significant reduction of contracture severity was found when McGhan Biocell implants were placed in Betadine-irrigated pockets.⁹ The authors speculate that a difference in the implant texturing process may at least partially explain the inconsistency.

Although a correlation between pocket irrigation with a microbicide and capsular contracture severity is not clearly substantiated, the proposition that the broad antimicrobial properties of Betadine should help reduce capsule contraction seems theoretically sound. Numerous bacterial species are routinely cultured from breast tissue, the surfaces of breast implants, and

the surrounding capsule. The existence of these positive cultures has led numerous authors to speculate that bacterial contamination of an implant or the periprosthetic space may establish a subacute infection, which either causes or contributes to capsule contraction. For example, Virden et al¹⁰ identified positive cultures in around 56% of implants with contractures and in 18% of implants without them. In addition, 91% of painful contractures were associated with positive cultures. The presence of periprosthetic bacteria may also explain the phenomenon of severe unilateral contractures.

Perioperative implant-related infections—both deep and superficial—are caused by the same microorganisms that have been cultured from the periprosthetic capsule or outer surface of breast implants. Most culture studies tested capsular tissue and implants removed from patients who showed no clinical signs of infection. Organisms most often identified are *Staphylococcus epidermidis*,¹⁰⁻¹⁶ *Staphylococcus aureus*,¹¹⁻¹³ *Propionibacterium acnes*,^{10,14,16} and α - and β -*Streptococci* sp.¹⁰⁻¹² Other microbes cultured less frequently in implant capsules include *Staphylococcus intermedius*, *Pseudomonas aeruginosa*, *Bacillus* sp, *Corynebacterium* sp, *Mycobacterium* sp, *Escherichia coli*, and *Klebsiella* sp.^{10,11,13,15-17} In a study of women with implants and symptoms of clinical perioperative infections, *S aureus* and *S epidermidis* were cultured most often.¹¹ All these organisms are “native” to breast tissue.¹⁷

After the FDA’s prohibition on Betadine use in breast implantation surgery, Adams et al began looking for other possible antimicrobials useful for pocket irrigation that might be as effective as Betadine against a broad spectrum of organisms. Betadine and several antibacterial solutions were tested in vitro against 5 microorganisms cultured from breast pockets or implant surfaces (*S epidermidis*, *S aureus*, *P acnes*, *E coli*, and *P aeruginosa*).^{1,18} The alternatives to Betadine were tested alone and in combination with one or two other antibiotics. Some combination breast irrigation solutions without Betadine were essentially as effective against the tested bacteria as the combination of Betadine/cefazolin/gentamicin. Still, the Betadine-containing irrigation solution was found to be slightly more effective against *Pseudomonas* sp than any of the non-Betadine-containing solutions. Because no single antibiotic successfully controlled all tested organ-

isms, Adams et al¹ recommend that a combination of bacitracin/cefazolin/gentamicin be used as a replacement for Betadine pocket irrigation.¹ Unfortunately, these antibiotics are quite expensive and not nearly as convenient as Betadine, which is the “gold standard” for preoperative skin preparation and therefore ubiquitous in operating rooms. As noted earlier, however, Betadine irrigation did not prevent infection in all patients in our series; one woman who underwent explantation demonstrated clinical signs of a deep perioperative pocket infection.

Our investigation found no evidence of patch or shell delamination. Furthermore, tested mechanical properties for the explants exceeded ASTM-required standards except for the elongation of the textured shells. These results apply only to Mentor saline implants, and more study is needed of all manufacturers’ devices before researchers can determine whether and when Betadine undermines the integrity of breast implant shells. Although our study was small, we found no evidence to support the FDA’s prohibition on Betadine use for breast pocket irrigation with Mentor implants. The addition of Betadine to saline filler solution does seem to damage implant shells and lead to early device failure. However, this intraluminal use of Betadine differs greatly from the common practice of Betadine pocket irrigation, which is done once. In this context, contact between an implant and extraluminal Betadine is transient and may not produce the same results as Betadine and saline solution in a sealed environment. ■

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