Trends-in-Medicine

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SUMMARY

♦ Use of Allergan's Botox continues to grow, and Inamed's competing product, Reloxin, is about two years away Doctors are not dissatisfied with Allergan, but they would switch quickly and substantially to from Botox to Reloxin if Reloxin is priced at least 10% less than Botox

♦ Medicis' Restylane has captured a lion's share of the dermal filler market Inamed's Captique is not considered a threat to Restylane, but Inamed's Juvederm could be – but it appears to be about two years away

♦ Cosmetic surgeons would like the FDA to allow silicone breast implants back on the U S market, but they are dubious that it will happen this year There is no pent-up demand for silicone implants, and if they are approved, doctors predicted they will capture about a third of the market in the first year, about 40% in the second year, and half the market by the third year, but use may stabilize there for a while

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COSMETIC SURGERY UPDATE

Nearly 500 cosmetic surgeons – dermatologists, oral & maxillofacial surgeons, otolaryngologists, general surgeons, plastic and reconstructive surgeons, ophthalmologists, and other specialties – were in San Diego for the American Academy of Cosmetic Surgery (AACS) meeting January 27-30, 2005 The hottest topics were botulinum toxins, lasers, surgical techniques, and breast augmentation Dermal fillers were not the focus of many talks, but doctors insisted they are still a mainstay of most practices Twenty-five cosmetic surgeons were asked about their use of these products

BOTULINUM TOXINS

ALLERGAN'S Botox (botulinum toxin-A)

Doctors continue to be big fans of the cosmetic use of botulinum toxin, and virtually every doctor questioned is using it A Georgia doctor said, "I tell patients that Botox is the best thing for **young** Moms since peanut butter and jelly "

Discussions at this meeting focused on Botox since it is the only FDA-approved product, and most of the sessions on Botox were standing room only The talks dealt mostly with techniques and tips on how to obtain the best results with Botox Speakers were not trying to convince anyone of the cosmetic value of Botox; these doctors already are believers Rather, experts reviewed solutions to problems that come up, ways to avoid those problems, ways to combine Botox and dermal fillers, etc

Botox use is increasing slightly as word-of-mouth spreads, but, among these doctors, almost exclusively for facial procedures Very few sources said they are using Botox for migraines, and almost none are treating hyperhidrosis (sweating) or other conditions

Dermal fillers were described as separate but complementary to Botox, and generally had little effect on the use of Botox, neither increasing nor decreasing its use If anything, fillers have confused patients a little A doctor commented, "Patients come in asking, 'Is this (Restylane) better than Botox?'" A Georgia doctor said, "If anything, Botox has boosted fillers by bringing more people to the table "

Sources showed little reaction to Allergan's most recent price increase for Botox Doctors said they didn't understand the price increase, suggesting it was simply profit-taking, but they insisted they are not resisting it in any way and generally are not angry with Allergan Most sources said they have absorbed this latest price increase instead of passing it along to patients One doctor commented, "We generally will absorb two or three price increases before we raise the price to

patients " Another said, "I have no ill will (toward Allergan over the price increase), but I don't understand it "

The situation is nothing like the stent market, where Johnson & Johnson's near monopoly several years ago had cardiologists champing at the bit for another stent – and which led cardiologists, almost overnight, to switch stent brands when a competitor (Guidant's MultiLink) got FDA approval Rather, Allergan has a very good reputation among cosmetic surgeons They are not anxious for a competitor to enter the market, but having another option is viewed as a positive A Midwest doctor said, "It would be nice to have some competition with Allergan " A Nevada doctor said, "It is a quality company "

INAMED'S Reloxin (dysport, botulinum toxin-A)

The pivotal Phase III trial was completed in mid-January 2005, but an investigator said it will take four to five months to analyze the data This trial (Study 52120) is a randomized, double-blind, U S /Canadian study comparing 50 units Reloxin to placebo The primary endpoint is the score on a visual wrinkle evaluation scale

The investigator said Inamed will not file Reloxin with the FDA until another trial is complete – the ongoing open-label trial – and that is likely to take another year The data from the open label trial are expected at AACS in January 2006 Another expert said, "Inamed will file in a year, and be approved by 2007 Typically, the FDA wants injection vs placebo at the labeled dose, and a re-injection protocol of one-year duration I expect the end of the re-injection study soon "

How does Reloxin compare to Botox? An expert said, "They are fairly equivalent I expect dysport will have the same effect as Botox, but they are not the same material, so there will be slight differences Dysport diffuses a little more than Botox, based on studies in cervical dystonia and blepharospasm "

Reloxin already is on the market in 70 countries to treat spasticity and neurological problems, and it was approved in South America in 2002 to treat frown lines A New Zealand doctor said, "I prefer dysport because it lasts longer than Botox – and doctors make more on it The vials cost the same (as Botox), but you can do more patients out of a dysport vial "

There was little excitement among doctors about Reloxin at last year's AACS meeting, but it was creeping into discussions a little more this year An Australian doctor said, "Dysport is a fraction cheaper, and some patients find it works better, but I haven't had any problem with dysport, so there is no need for me to change " A California doctor said, "Everyone will try Reloxin to see if it lasts as long and is as comfortable to patients…But people are very happy with Botox, so before anyone will change, we will need legitimate studies and our own experience with it People will experiment with it to get hands-on experience "

Among the questions/issues doctors have with or about Reloxin are:

- **Unit conversion.** The working hypothesis is that 2 5 units of Reloxin equal 1 unit of Botox, but experts are not certain this is the correct conversion An expert said, "The ratio is likely to be closer to 4:1 instead of the 2 5:1 that is being posited Fifty units of Reloxin may do as well as 20 units of Botox, but I suspect not "

- **Price.** The pricing of Reloxin is likely to have a significant impact on how strongly and how quickly it is used One doctor suggested sampling may help spur Reloxin use, "If I were Inamed, I'd give samples " Another doctor said, "Botox will hold a lot of market share because patients will ask for it by name "

Doctors estimated that if Reloxin is priced at:

- **Parity with Botox:** Uptake will be very slow Doctors would experiment with Reloxin, but market share would remain low at least for the first year One doctor said, "I'll stay with Botox, unless Reloxin is cheaper or has a longer shelf life than Botox The profit is very small for physicians, and we know Botox " A Florida doctor said, "If the price were the same as Botox, I would only try it if it were as good as Botox "

- **A 10% discount to Botox:** On average, Reloxin would quickly capture 45% market share A West Coast doctor said, "Most patients would choose this if it were less expensive "

- **A 20% or greater discount to Botox:** On average, Reloxin would capture 73% market share at this price point A Florida doctor said, "I'd cross right over if the price were 25%-33% lower with dysport " A Nevada doctor said, "If the price were 20% less, then I would look at Reloxin hard If it works just as well, I'd probably switch over 70% to Reloxin, but I would still use Botox; you have to have both " A California doctor said, "If Reloxin were 20% cheaper, I'd switch over to it completely " Another West Coast doctor said, "I'd stock a lot more Reloxin at this much of a discount because it is a better buy for patients " A Georgia doctor said, "The price discount would have to be 50% for me to switch to Reloxin from dysport "

- **Technique.** An expert said, "If I switched to Reloxin, I would be insecure for six months, but by then I would work out how to use it, and I'd be happy…Dysport requires more precision in giving it, but that is not a major difference " A California doctor said, "People will jump on dysport because of price, but they will make mistakes because it isn't used the same "

- **Relationships.** Allergan got a lot of praise from doctors for its support A doctor said, "Allergan does a lot of education with Botox – workshops, support, information

brochures – and it would be churlish to accept the education opportunities and use another product "

➢ **Diffusion.** There has been speculation that Reloxin diffuses more than Botox An expert confirmed this, saying Reloxin diffuses about 1 cm

Other botulinum toxins

Doctors are very leery of non-FDA-approved botulinum toxins after the recent problems in Florida where four people had to be hospitalized with botulism after being injected by an unlicensed Florida physician The FDA investigated and determined that none of the patients was given Allergan's Botox Rather, they were given massive doses of an unregulated, unlicensed, and unapproved bulk botulinum toxin distributed by a Northern California maker of research material However, the incident was a wake-up call for doctors who had been purchasing Chinese botulinum toxin or other botulinum products from outside the U S Any doctors who admitted to having used non-approved sources said they have stopped doing that A New England doctor said, "I'm impressed with how Allergan handled the Florida problem "

There are at least two other botulinum toxins in development that may gain FDA approval in the future Doctors said they will not be afraid to try these agents when and if they are FDA-approved

- **MENTOR.** The Wisconsin Alumni Research Foundation (WARF) licensed exclusive manufacturing and marketing rights to Mentor to a proprietary botulinum toxin technology that was developed at the University of Wisconsin-Madison The deal calls for Mentor to pay WARF a royalty on sales plus unspecified regulatory milestone payments This product also has no protein attached

- **MERZ'S NT-201.** Merz used to have a license to Botox from Allergan in Germany, and it is just starting human trials of its own botulinum toxin There reportedly is no protein in this product, which may avoid antibody formation By comparison, Allergan reduced the protein load in Botox by 80% An expert said, "We thought there would be an advantage to having protein, but with the pure botulinum toxin, we find protein is not necessary "

  In June 2004, researchers reported on a 466-patient cervical dystonia study, in which patients were given NT-201 by intramuscular injections (at 70-300 units) or standard botulinum toxin

NT-201 Trial in Cervical Dystonia

Measurement	NT-201 n=213	Standard botulinum toxin n=207	p-value of NT-201 vs. standard botulinum toxin
Change from baseline at Week 4			
Primary endpoint: Toronto Western Spasmodic Torticollis Rating-Severity score (TWSTRS-Severity)	-6 6 (p< 05)	-6 4 (p< 05)	Nss
TWSTRS pain subscore	-0 4 (p< 0001)	-0 6 (p< 0001)	Nss
Pain by Visual Analog Scale (VAS)	-8 8 mm (p< 0001)	-11 8 mm (p< 0001)	Nss
Median duration of effect	110 days	109 5 days	Nss
16-Week results			
Adverse events	28 1% (n=231)	24 1% (n=232)	---
Dysphagia	25 patients	19 patients	---
Adverse events common to both arms	Headache, fatigue, and diarrhea		---
Adverse events more common in a particular arm	More arthralgia	More headache, fatigue, and diarrhea	Nss

DERMAL FILLERS

Dermal filler use is strong On average, doctors reported filler use was up 22% year-over-year A Midwest plastic surgeon said, "A lot of TV shows have really boosted cosmetic surgery, making it more acceptable "

Outlook for Filler Use in Two Years

Company	Product	Physician expectations for usage
Medicis	Restylane	60%
Inamed	Captique	25%
Inamed	Juvederm	15%

MEDICIS' Restylane

Restylane is king of the dermal fillers It is the predominant filler for every doctor questioned Sources have been satisfied with the results, and they have no complaints about the product or the company Among the comments doctors made were:

- "Inamed's Hylaform is comparable to Restylane, but Restylane got there (to the market) first, and Restylane is laboratory-manufactured, while Hylaform comes from rooster combs "

- "I use mostly Restylane because it lasts a long time, there aren't the allergy problems of the collagens, and the results are great "

- "I used (Inamed's) Hylaform before Restylane, but it doesn't have the longevity of Restylane But Hylaform has less short-term redness and swelling than Restylane, so it has a role in certain patients "
- "Restylane doesn't require skin tests, it's not collagen, and it lasts longer than collagen That's why I use it…Patients like Restylane, and then they want something more permanent, but I tell them I don't have experience with anything more permanent "

Side effects and complications are in the expected range, primarily occasional bruising or lumpiness One doctor said, "There is immediate bruising once in a while, but it is not common Abscesses are very rare; I've never seen one " Another doctor commented, "There is only the normal bruising and swelling and occasionally a little lump, but the patient can massage that in the shower "

Restylane sales reps were emphasizing these advantages to Restylane: purity, durability, and viscosity They also indicated that Medicis will do more direct-to-consumer advertising in response to Inamed's introduction of Juvederm in the U S

On average, Restylane patients come back every 6 5 months – and they ***are*** coming back A Nevada doctor said, "Women who are very sensitive come back in about four months, but the average is six to seven months "

Nothing on the market or on the near horizon is viewed as a competitive threat to Restylane Doctors are mildly interested in Medicis' follow-on products, Perlane and Fine Lines, but they consider them mostly line extensions that will further solidify their Restylane use, not as major market expanders One doctor said, "Perlane and Fine Lines work fine, and I'll use them, but they won't give a boost to Restylane " Another said, "Perlane and Fine Lines will be useful additions "

INAMED/GENZYME'S Captique

This non-animal stabilized hyaluronic acid was approved by the FDA on December 2, 2004, but doctors at AACS were generally unfamiliar with it There was no excitement about Captique, and no sources had tried it yet Few sources thought that Captique, which lasts up to a year, compared to Restylane's six months, would impact their use of Restylane A Midwest doctor said, "Captique probably will be competitive with Restylane ***if*** it is priced the same or lower…I just ordered it I probably will use both Captique and Restylane Some patients want Restylane, but some want the newest thing…Captique is identical to Restylane " Another doctor said, "I think Captique will behave the same as Hylaform…It is basically the same material as Hylaform " A Nevada doctor said, "I just got a flier about Captique I don't know how it will do If it is priced lower than Restylane, that would help, and I could tell 'shopper' patients that it is something to try "

INAMED'S Juvederm

Juvederm is unlikely to get FDA approval for at least 18-24 months In October 2004, Inamed announced that enrollment in the trial was nearly complete, but with 12-month follow-up, that means Inamed probably could not submit the data until early 2006, with a decision coming in late 2006 or early 2007

Many doctors were familiar with Juvederm, and several predicted it may be a viable challenger to Restylane Comments included:

- *Canada:* "I think Juvederm may give Restylane a run for its money Juvederm is much closer to Restylane in duration than Hylaform is…We've had Juvederm in Canada for three or four years, and it behaves much like Restylane, but I still use mostly Restylane because the majority of my experience is with Restylane I don't have a confidence level yet with Juvederm…At the present time, Restylane rules…Fillers aren't like Botox, where use is all about technique With fillers, you really need to know about the impurities…Why Inamed licensed Juvederm when it had Captique and Hylaform most likely is due to Juvederm's (longer) duration of action…I think the choice of product (Restylane or Juvederm) will be mostly a marketing issue – whoever markets the best… Inamed could bundle Juvederm, especially if it gets silicone breast implants approved "
- *Ohio:* "I know about it, but I'm happy with what I use It's not an advance "

In fact, doctors were so happy with Restylane and so lacking in enthusiasm for other fillers, that they were unable to predict the market shares for Restylane, Captique, and Juvederm They simply insisted Restylane would remain the No 1 filler

SANOFI-AVENTIS'S Sculptra (also known as New-Fill)

This was FDA-approved in August 2004, to correct facial fat loss in people with HIV, and it is getting a lot of attention Sculptra does not appear to be a threat to Restylane, and it is likely to remain a small share of the filler market, but many doctors have just started or are planning to start using it New-Fill is comprised of poly-L-lactic acid microparticles (40-63 microns in size), a substance that has been used for years in other products, such as sutures A Pennsylvania doctor said, "I use 90% Restylane but about 10% Sculptra "

BIOFORM'S Radiance

Radiance, which was purchased from Bristol-Myers Squibb, appears to have lost favor with these doctors Radiance is comprised of 35% calcium hydroxylapatite (CaHa) and 65% gel components, in microspheres that are 25-45 microns in

size that act as scaffolding for tissue ingrowth Radiance has been FDA-approved for use in ophthalmology, orthopedics, and dentistry, for more than 20 years It is FDA-approved for soft tissue marking in any anatomical location, vocal cord injection, and oral and maxillofacial augmentation, but does not yet have FDA approval for use as a facial implant

However, doctors are using Radiance off-label to treat nasolabial folds, lip rhytids, glabella, chin rhytids, cheek depressions, prejowl, acne scars, earlobes, etc An Ohio plastic surgeon said, "Radiance doesn't last as long as expected, and it has a tendency to be lumpy " Another doctor said, "I wouldn't try Radiance until it has been in the U S a while (at least a year), even though it has been in Europe a long time – remember Phen-fen (Wyeth's diet drug that got pulled from the market) " A third doctor said, "I tried Radiance a little, but there was too much hardness, and you have to be careful about injecting it too superficially It's possible I might use Radiance after Restylane for longer-term results " A California doctor commented, "I don't like Restylane, and I don't use it I prefer Radiance; it's longer-lasting "

BREAST AUGMENTATION AND RECONSTRUCTION

Only two manufacturers have breast implants on the U S market, Inamed and Mentor Each has its proponents, and many doctors use both brands Both companies have good reputations with these doctors Mentor's recent price increase was taken with a grain of salt, but doctors expect Inamed to follow suit soon with its own price increase A Nevada doctor said, "Inamed stands behind its products They are pricey, but you get what you pay for And the products are well-researched " An Oklahoma doctor said, "I expect Inamed to raise its prices, too They mirror each other " A New York doctor said, "Inamed and Mentor made a commitment to the field, and they stand behind their products "

Silimed, a Brazilian company, is looking to bring its implants to the U S in 2006 if the FDA opens the door to silicone implants later this year A Silimed rep said his company offers:

- Polyurethane implants with a textured surface
- Anterior valve saline implants, which the company hopes to launch in the U S in the spring of 2005
- Two types of saline implants that Inamed and Mentor don't have – pre-filled and flat posterior valve implants

The Silimed rep also claimed his company's silicone implants use newer technology and have "much lower" deflation rate than U S competitors Mentor officials, of course, disagreed, insisting there were no advantages to the Silimed implants and challenging Silimed to prove its deflation rate In clinical trials, Mentor implants have been shown to have a 3 7% deflation rate at seven years

Eurosilicone also makes silicone implants that are used in Europe A West Coast doctor said, "We use these routinely, but we need specific FDA permission to do so "

Saline implants

Demand for saline breast implants is strong, up an average of 26% year-over-year among these sources, and the prediction is for this trend to continue through 2005 There appears to be no weakness in breast augmentation procedures because of the economy, pricing, or anything else

Doctors are not anxious for a new saline breast implant supplier in the market, and a new competitor might find this a hard market to crack Sources pointed out that Inamed and Mentor have been in the market for the long-haul, have good products, and support the field A doctor commented, "A new saline implant wouldn't change what I do We don't need another supplier They couldn't improve things much "

Silicone implants

Safety concerns caused the FDA to institute a "voluntary moratorium" on silicone breast implants in 1992 because of safety concerns Women who want them for reconstructive purposes can get access, but they are not allowed to be used for cosmetic breast augmentation Thousands of lawsuits were filed by women who claimed they had developed serious ailments, such as connective tissue diseases, neurological diseases, and cancer as a result of the implants, and the manufacturers agreed to a $4 billion class-action settlement Then, in 1999 the National Academy of Sciences' prestigious Institute of Medicine issued a report concluding that there is no convincing evidence that silicone implants were connected to systemic diseases such as rheumatoid arthritis, lupus, or scleroderma

In October 2003 an FDA advisory committee voted 9-6 to recommend the FDA approve Inamed's request to be permitted to market silicone breast implants once again but "with conditions " However, shortly after the meeting, the panel chairman changed his mind and urged the FDA to reject the committee's recommendation That's exactly what the FDA did in January 2004 The FDA turned Inamed down, saying it wanted additional safety testing, including new rupture testing

Inamed has submitted supplemental data, and the FDA's General & Plastic Surgery Devices Committee is scheduled to take this issue up once again at a three day meeting, April 11-13, 2005 While most doctors interviewed at AACS believe this panel will recommend approval again, many doubted that the FDA would follow that recommendation One commented, "The FDA will continue to be paternalistic – but I expect Inamed and Mentor to bring (satisfied) patients to the panel " Another said, "I think the panel will be stronger than it was last time, and the FDA will approve silicone breast

supports approval of the implants That's what this should be about "

➢ **Media response.** If the FDA did approve silicone breast implants, the media are likely to flood newspapers and the airwaves with stories about women who oppose approval and/or who claim to have been harmed by silicone implants, and the FDA has to be aware this is the likely response Several media sources confirmed this is their plan, and Zuckerman said, "I think there would be very embarrassing stories coming out There's continuing research, and what has protected the implant makers so far is that they pay for most of the research However, more and more people are getting implanted medical devices of all kinds and there is increased scrutiny of those devices, including breast implants There are more devices, and there will be more problems "

Most – but not all – doctors questioned about silicone implants like them, believe they are safe, and prefer them to saline implants The most credible concern about silicon implants is capsule contraction There was no worry about connective tissue disease, autoimmune disorders, fibromyalgia, breast cancer detection implications, cancer risk, breast feeding implications, or rupture rates A California doctor who has performed more than 4,000 implants said, "Most of the claims are either financially-related or have to do with something else We had two similar cases with saline implants – malaise, bone ache, etc Nothing showed up on tests, but when we took them out, the patients felt better " A Florida doctor has two daughters who both got saline implants – and both got hard He said he would like to specialize in doing re-dos, "And then I want silicone " Another doctor pointed out that leakage can be an issue, "Leakage doesn't cause autoimmune disease, but it can cause significant local problems "

Perhaps surprisingly, there is little pent-up demand for silicone breast implants – now more commonly referred to as gel implants, and no source has a waiting list for silicone implants, though several doctors said they believe that silicone implants would help expand the market Reconstructive patients already have access to silicone implants, and if non-reconstructive patients are insistent, they also can generally get them by enrolling in a clinical trial, doctors explained Sources agreed that no patients are postponing the decision to get implants in order to wait for possible silicone approval this spring/summer Among the comments doctors made were:

- *Ohio plastic surgeon:* "The reality is that patients can get silicon breast implants if they want them Mentor has a study, and if a patient needs a lift as well as an implant, she can get approved for silicone But most women in my area are silicone-shy We are not Silicone Valley…I show patients both silicone and saline implants Silicone might feel more natural, but 20%-25% of patients have capsule formation, where the implants get hard And saline implants require a smaller incision and are adjustable for individual patients…Unless there is a compelling reason to use silicone, saline is the way to go – the incision is smaller, there is less paperwork, it's adjustable, and there is less capsular constriction "
- *Oklahoma doctor:* "The implant companies may be too aggressive in their predictions on the market for silicone implants because of cost They may get less than 50% of the market And silicone implants may not be a market expander "
- *Massachusetts:* "There's no reason to rush into silicone implants There is no medical necessity for them I'd wait another year If they are approved, there won't be a stampede to use them There's no waiting list, and people think there are problems with them Silicone is not a market expander "
- *New York plastic surgeon:* "Doctors and industry are more interested in this issue than women There is a whole generation of women satisfied with saline No floodgates will open if the FDA approves silicone implants And the attitude toward silicone may depend on the age of the surgeon Doctors over age 55 who used silicone are much more disappointed in saline than younger doctors who have no experience with silicone…Silicone implants would be a market expander because there is a percentage of women who choose not to have implants because they don't want saline "

On average, these doctors predicted that the share of the breast implant market that silicone implants would capture will be:

➢ **Year 1. 32%.** A West Coast doctor predicted silicone implants would expand the breast implant market about 10% the first year, adding, "Silicone is more expensive, and you can't put them in with a transumbilical approach (TUBA), so I'll still be using 75% saline in a year, but women prefer the feel of silicone when they touch it " A California doctor said, "It is a cost issue, and recovery from TUBA is fast – two or three days vs the two to three weeks with a transaxillary approach (with silicone implants) "

➢ **Year 2. 43%.**

➢ **Year 5. 65%.** By the end of five years, sources believe silicone implants will be used for more than half of all breast augmentation procedures

The problem with greater adoption appears to be three-fold:

1. **Fear by patients and some doctors.** A Florida doctor said, "I'd use silicone 100% if patients let me, but some patients are scared " A Southwest doctor said, "Patients are pretty well educated There is still a stigma to silicone, so patients say either, 'Fine, I'll accept saline,' or they request it specifically " A California doctor said, "I wouldn't use silicone It's too much risk "
2. **Price.** Currently, silicone implants cost about $1,800-$2,400 a pair, compared to about $800-$1,200 for saline implants, and doctors pass this cost along to patients That's what they expect to do when and if silicone is

allowed back on the U S market – to pass the price differential along to patients But no source plans to tack any additional markup onto the price Patients are very price sensitive, doctors explained One said, "There is a lot of price shopping " Another said, "When a woman decides she wasn't breast implants, cost doesn't matter…but a lot of women prefer saline because they feel it is safer " A third said, "The major reason patients opt for saline is cost… I think the manufacturers are too aggressive on their estimates about the market share for silicone because of cost Patients are very price sensitive, especially breast augmentation patients "

3. Younger doctors often have no experience with silicone.

All silicone implants made for the last 10 years or more have been gel, what doctors refer to as cohesive This means that you can cut one in half, and the two halves remain whole, nothing drips out While each silicone manufacturer – Inamed, Mentor, Silimed, etc – makes superiority claims for its gel implants, doctors consider them fairly comparable One doctor may prefer Inamed implants, and another Mentor implants, but many use both fairly equally, and no sources saw significant differences in the two company's products A plastic surgeon commented, "Mentor implants are wider and less projecting; Inamed implants are narrower, with more projection, but I use them half and half " A New York doctor said, "Today's silicone is not yesterday's silicone All the silicone implants today are cohesive "

In December 2004, Inamed filed its next-generation BioDimensional Cohesive Silicone Gel Matrix with the FDA Sources, including Inamed implant fans, were not especially impressed with this implant None described it as substantially better than anything else currently available, and there was no excitement or anticipation about this product However, this could be due to lack of information about it, and they may get more enthusiastic when detailed on it, but, at this point, no one plans to hold off on use of other silicone implants (either from Mentor or Inamed) to wait for this newer product Inamed may have a lock on the use of "cohesive" as a brand name, but the other silicone manufacturers also claim their silicone implants are cohesive Comments included:

- "It's too early to tell if cohesive gel will be less capsular constrictive than other implants "
- "I'm in the BioDimensional Cohesive study I love them If you cut them, they maintain their shape, so they are more solid, more gummy-bear-like, so there is a chance to use the tear drop design Supposedly, there is less chance of rupture or leakage with these, but only time will tell "
- "All the new silicone implants are roughly the same "
- "Other cohesives don't leak, but their shapes shift The BioDimensional Cohesive doesn't change shape If I had both regular silicone and BioDimensional Cohesive available, I'd prefer flexibility The firmness (of BioDimensional) sounds great in theory, but if they aren't put in perfectly, you will have shape problems It is critical to make a good pocket, so they are more technically-challenging…I certainly wouldn't wait for them "
- "I stay away from anatomic shapes because they rotate and cause problems "
- "I like the tear drop design; it's anatomic "

IMPRA'S Pocket Protector

This device, developed by Dr Mark Berman, does not appear to have caught on much since last year, but the idea is interesting The pocket protector facilitates breast implantation with an e-PTFE bladder that lines the breast pocket in order to reduce the risk of capsule formation and rippling, while containing the implant within a confined space The material is FDA-approved but the breast application is off-label

♦