

**ABDOMINAL WALL REPAIR USING VERITAS COLLAGEN MATRIX
SSM ST. MARY'S HEALTH CENTER
RICHMOND HEIGHTS, MISSOURI
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ANNOUNCER: This event is being sponsored by Synovis Life Technologies. Welcome to SSM St. Mary's Health Center in Richmond Heights, Missouri. Over the next hour you'll see the premiere webcast of the complex abdominal wall repair using Veritas Collagen Matrix. Dr. Jonathan Limpert performs the procedure using Veritas Collagen Matrix, an exciting alternative to currently available synthetic and biologic meshes. At the conclusion of the procedure, Dr. Limpert will narrate a slide presentation highlighting his results with Veritas Collagen Matrix, including patient follow-up of greater than two years. OR-Live makes it easy for you to learn more. Just click on the "request information" button on your webcast screen and open the door to informed medical care.

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Hello, I'm Dr. Jonathan Limpert, coming from St. Mary's Hospital in St. Louis, Missouri. Today we're actually doing a complex abdominal wall repair due to a fistula. Right now what we've done is we've gone ahead and gotten the specimen taken out and we'll go through some of the patient's history. Today we'll be using Veritas, a collagen matrix product by Synovis, to repair this abdominal wall hernia. Right now what we've got is -- as you'll see in the abdominal cavity, we've taken out a fairly sizable piece of small bowel that was actually adherent to the mesh and actually adherent to her bladder right here. And now what we've got is we've got a fascial defect, as you see all the way around here. And we've excised a pretty good portion of the mesh, and there's no more foreign material left within the abdominal cavity here. This is the small bowel anastomosis, and we've completed that portion of the procedure. And now what we're getting ready to do is prepare to irrigate out the abdominal cavity with a bacitracin mixture, and then we'll be measuring for the Veritas Collagen Matrix. Do you want to hold that up? This patient is a 72-year-old female who underwent a rectus abdominis flap for a mastectomy, a reconstruction for a mastectomy, and she has developed a hernia over the last 10 years. This was repaired initially with a mesh product, and now she has developed a fistula through that mesh product. She was taken back to the operating room about seven weeks ago and underwent an excision of mesh and then repair of the abdominal wall hernia with Collamend. And Collamend is actually a cross-linked porcine collagen matrix, and the problem with the cross-linked products is that they do have a synthetic component to them due to the cross-linking. They will, quote, "stick around," and so when you have an infection like she had, it will continue to be infected. So not only did she have mesh but she also had a cross-linked product, which caused us a great bit of difficulty here. As she was then -- I was then asked to see her in regards to her fistula, and she had a persistent fistula that now we've decided to remove the fistula, repair the bowel, and not repair abdominal wall. And of course we can't use mesh. She's actually growing out of this wound. She's growing methicillin-resistant staph aureus, and she's also growing candida albicans. So she has been treated for about a week and a half now and has been on parenteral nutrition for approximately three weeks and has maintained her nutritional status to where we think it's now safe to begin this repair.

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So what we're going to do, before we choose our size of the Veritas, we're going to measure the defect. One of the good qualities about Veritas is there's no real stretch that you have to account for in the field. You put this in -- looks like 12 -- you basically put this in to encompass your defect and you don't have to account for any large stretch -- 12x12. So therefore we do not have to do any back table preparation of this by any manipulation. Okay. So I think the size that we're going to choose here is the 10x16 centimeter sheet; our defect was actually 12x12. And you actually see how easy it is actually to prepare this product and how we can actually just trim it. Let's have the product up here. Go ahead and open it up. The other good quality about the Veritas product is there's no rehydration period. This is actually a wet substance and can be used right away. In addition, there's a couple other products on the market that require a certain side and as you can see with the Veritas, the sides are actually the same, so there is no wrong way to put it in, which is another redeeming quality in trying to figure out which side is up and which side is down. So what I usually do is we'll take this, and you can actually insert the Veritas in several fashions. You can use it as an interpositional graft or you can use it as an underlay. I think when you're repairing these large defects like this, using it as an onlay is not advisable. I would try to stick to the same principles we use with synthetic mesh. What we're going to be using is actually a nonabsorbable prolene suture, and I use a 2-0 prolene. And we'll circumferentially run that around. I actually will probably use four of them in this instant. And she actually has some not so great tissue on the right lateral aspect of her abdominal wall, but we do have some fascia there, which is going to be -- looks like quality tissue that we can actually sew to.

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So we're going to start by first just placing the product within the abdominal cavity, and like I said, there's no preparation on this. We did use an antibiotic irrigation, but that's just be preference due to the fact that she was infected. And the comforting thing with this is this is not a cross-linked product, so in the face of this infection I feel comfortable that we will have no problems with getting this infected. And I've actually used this quite a bit in this similar circumstances removing mesh products and then placing it without any concern for the infectious component. So what we'd like to do is start one side of the repair. And like I said, we'll be using a nonabsorbable suture. As you can see, it's very easy to sew with. It's a very strong material. I'm using 2-0. We've actually field-tested it with myself and my residents from St. Louis University and tried to pull 0 prolenes through this, and it's very difficult. This is a very tough product and very pliable, though. It's very easy to work with. Let's just tag this in. In my current series using Veritas in this particular application, I've done approximately 27 cases now, and they've ranged from open abdomens for pancreatitis patients with necrotizing pancreatitis, patients with intra-abdominal abscesses and intra-abdominal catastrophes -- we'll just take a larger [ridge] there -- who have required an open abdominal approach.

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We did have one failure, and I'll actually talk about some of these cases in a PowerPoint presentation at the end of this procedure. And the actual one failure that we had was -- I believe was due to an early application. It was a patient that had necrotizing pancreatitis and was operated on by my partner prior to me operating on her and had the Veritas placed at the first surgery. She had pseudomonas, not only colonization but also a significant amount of pseudomonas within the abdominal cavity, and the Veritas was lost due to that. She subsequently had a repair after -- I believe she had another 10 operations to debride her and remove retroperitoneal abscesses, and she had a great repair. And actually, on my most recent follow-up with her, she's actually pregnant now and plans on delivering her first child. She does have a little bit of laxity to the abdominal wall. However, there's not evidence of recurrence by CT scan or by physical examination, and she had application of the -- don't pull -- she actually had application of the wound VAC -- and we'll talk about that

at the end of this procedure -- which I think works really well in these particular cases. It provides for good angiogenesis, good wound contraction, and I think these patients heal a lot better and I think we're getting a stronger remodeling to the Veritas. The idea behind the Veritas product is that it will take on cells from the host tissue and remodel into the adjacent tissues. And you can see it actually is quite pliable, very easy to sew. May I have the scissors? And I know that our nursing staff really likes to work with it because they don't have to do that rehydration period. It's just one less step, especially when you're doing these cases that aren't necessarily scheduled. These patients are usually sick or have been in the operating room for quite some time, and any other -- any added 30 minutes can be detrimental.

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What we'll probably do is start another stitch. I usually use four stitches on a defect this big and kind of run them together. Let's have a [snap]. And scissors. As you see as we're sewing around this, you don't need to have a large [purchase] on the fascia. I mean, this is just abutting the fascia. Go ahead right there. This is just abutting the fascia, and so it's not like the typical mesh where you're trying to get that significant fascial bite. We've cleaned this off. Our preparation work prior to placing the product involved removing some of the attenuated fascia, and so now we're back to some stronger tissue. And like I said, you can place it in multiple areas. If you feel more comfortable with an underlay, I think that's acceptable. I think in these larger hernias I prefer to do it as an interpositional graft, and I've had good success with that particular approach. When using this VAC product, you'll start to see this granulate almost within about the first five days, you'll see some nice healthy pink tissue, just like you would in an open wound that kind of covers the -- let's go ahead and tie these together. Want to retract for me? And you see that within the first five days. Can you cut that? Take that right there. And then come back on the other side of that and hold that up. Swing up this way.

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The superior part of this wound is quite difficult. We're actually right at the umbilicus. We did have good fascia there, so we chose not to excise the umbilicus. I think there is a point to be made, though, when using this product in the contaminated or infected fields is that I think we want to try to avoid gross contamination because some of the more resistant strains of staph and pseudomonas will have a tendency to degrade almost any biologic product that you put in there, and so I think you do have to start with a contaminated wound as opposed to a frankly infected wound. Since we've begun using this product, our referral base for these abdominal wall catastrophes has increased dramatically, and it's amazing to know how many of these problems actually exist out there. And I think with the widespread use of synthetic mesh, which in the right setting does provide a great repair, I think we're still seeing a lot of patients who are developing fistulas to different products, requiring a removal. This patient actually had her Collamend removed at the bedside. It was actually coming through the fistula track within the abdominal wall and had not incorporated at all. And actually, the sutures had actually disengaged from the fascia. Tie this needle and we're going to trim some of this. Watch your arm there. Let me have that [curve mass]. So we're going to go ahead and trim some of this. And like I said, you do not have to account for a certain stretch. This product will give some laxity, all biologics do. Okay. Let's go right here. The other aspect to this product that's worked quite well is I have used -- before the larger pieces actually came out, I had done some patchworking or quilting of this product using the same 2-0 prolene technique. That was actually used on the patient I talked about with the necrotizing pancreatitis and it worked quite well. And you'll see in the slides that we show here in a minute some of the -- pull some that way. Pull straight up. Okay. She has a very thin fascial layer but does have some good consistency to it. I think I like the interpositional technique because I think it makes more sense to me in the remodeling process that those cells will migrate right across the top as opposed to the underlay technique, which may be actually abutting the peritoneum. Let me have the scissors. Can

you hold that for a second? This is some old suture material that we're going to remove. Okay, let's go ahead and hide this needle. Let's have another stitch. Start over -- yeah, let's go right there. Stitch.

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She actually had some mesh within her that looked like it was starting to erode into the bladder, which we have seen significant migration of mesh and seen it erode into the bladder, seen it erode into the bowel, causing significant problems. And this has definitely eroded into the bowel, causing her persistent fistula. Couple millimeters. I'm all right. I think one of the remarkable things, too, about using the Veritas product is that I have gone back in on patients who've had the product placed. I've repaired a couple epigastric hernias on patients who have had coronary artery bypass grafting who had the methicillin-resistant infection, the MRSA, and used it in that application, and when we went back in, actually the only adhesions were the adhesions at the actual prolene suture line. The product itself actually had no problems with adhesions. So we're coming around the corner here. We have about a third of the product left to place in. And fortunately, for today while we're filming this, it looks like I cut it to a good size, so we won't have to patchwork it. I would prefer not to, and that's the benefits, too, that we've seen larger sizes coming out of Synovis of this product, which I think really helps in these larger defects. I think all of us fixing these hernias feel more comfortable when we use one solid sheet. I think the other good qualities about using these is their pliability. You know, the abdominal wall -- patients that have abdominal wall, the chronic pain associated with placement of mesh due to the scarring and the rigidity of that mesh repairs is -- I believe the size on this, Rishiki, was a 10x16 sheet. The largest that we have in the armamentarium is a 12x25 sheet.

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And we can go ahead and get the wound VAC sponges open. Let me have a clamp. Let's get some suture material in there. Histologically, we've actually taken samples and seen that this will remodel into that host tissue. And that regeneration that you see -- Rishiki, are our counts correct? That regeneration that we see, we've actually seen in both the animal model and in the human model on the biologics. And as you can see as we finish, this is not tight. This is somewhat lax. We don't want any tension, just like in a good synthetic repair. I'm going to finish putting the sutures in here. Scissors, please? And I will take and actually use a 2-0 Vicryl at the interface where these knots are. When you tie them together it tends to be a little cumbersome. You may get a little gap there, so we'll take a 2-0 Vicryl and -- when you look in the animal model, actually the Veritas product has a regeneration or remodeling period of about four weeks to where when that tissue is taken out it really mimics the native tissue. There's a knot up here. This may not be a necessary step; however, it allows my team to count and make sure we haven't left anything behind. Let's go on down here. There's another knot on the other side there. We'll need the Adaptec as well for the -- okay. There we go. As you can see, she does have quite a soft tissue defect here, and she had a lot of edema and involvement of this, although her infection actually subsided quite a bit. We had actually gotten her to the point that she was not a high output fistula -- she was a low output fistula and her immune system had done a good job on it with the antibiotics. So let's have a pickup. Scissors? Let me have another 2-0 Vicryl.

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So I think the indications that I use the product Veritas is in this exact kind of case, the contaminated case, the case associated with a loss of domain, those patients that are ill and in the intensive care unit, have significant abdominal problems, and mesh is just not a good product for them due to the fact of the infectious complications and the issues with fistulas. So I think a couple of the problems that we see with mesh is the fistula formation, the chronic pain, and the infectious property, and with that, we really don't see that with this product. At this point in time what we're going to do is we're going to place the wound VAC. And like I said, I think the wound VAC really does well for this product. I think we get a lot quicker angiogenesis. It gets incorporated into the surrounding tissues. You see that

remodeling happen. Let's go ahead and see the sponge for the wound VAC. This is the wound VAC by KCI. This is actually a silver impregnated sponge, and on these contaminated cases I like to use this product first before we change over to the conventional sponge due to its anti-infectious qualities to it due to the silver impregnation. I'm fortunate enough to have the plastic surgery residents from St. Louis University, her wound VAC experts, to rotate with me. So we'll take a large curved [unintelligible] there. Let's go ahead and measure our sponge, Allison. So she's got a little bit of -- we've created a flap circumferentially around this to get the fascia to where we can get a nice layer to sew to and we can tell. When you're placing the wound back over this, I think it's important to use a nonstick, nonadhesive between this. These sponges do tend to stick at times to the underlying tissues. And what looks like a large piece in the beginning is quite a small piece once you apply the VAC. I think that's actually going to work pretty good. So we use this silver sheet first. Do you have the Adaptec? Why don't we cut that in half? That Bovie. Let's go ahead, yeah, and cut that in half. And with each application of the wound VAC I do use the Adaptec, especially in the very first few weeks until we get a nice healthy bed of granulation tissue over to protect the product. Let's have one more piece, Rishiki. Let's just cut a strip, maybe a couple of centimeters. Right there. Okay. So we place the wound VAC device in. I use the wound VAC probably in about 80 to 90% of these cases due to the significant amount of soft tissue that we usually see. Let me have a wet and dry sponge. Of the patients that I've performed this procedure on in these infected cases, I have seen no recurrences in those particular cases. In the initial cases using it in the epigastric region, which is a very hyperrecurrence rate even using synthetic mesh, up in the 30-40 percentile range, we did see some recurrences. Recurrence weren't as dramatic as the original hernias and occurred at about six to eight months and did require placement of laparoscopic mesh. These patients -- we did use that product due to the fact that they had a history or ongoing infection, whether it was a pulmonary issue or whether it was a sternal wound. So we probably need to cut these drapes back. Let's go ahead and have the scissors. So she was fortunate enough to have a defect right almost in the middle of her abdominal wall, which makes it easy for wound VAC application. Okay. Wet and a dry. So as we place the wound VAC, we're almost completed here. And we will talk about -- we'll have a slide presentation and go over some of the other cases that I've mentioned throughout this procedure. I could talk a little bit more about the specifics with the implantation of the product and various applications. Okay. Do we have our wound VAC? Plastic first. I don't think so. Okay. We're just about completed here. Scissors. So what we'll do is make a small hole in the top of this. We'll apply our vacuum system. And that completes our procedure. So our wound VAC is in place. We've got the Adaptec down, the wound VAC's in place, and we are now completed with the procedure and we'll go to our slide presentation.

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So we have completed our abdominal wall reconstruction in this 72-year-old female who had multiple fistulas. And during the operation we actually found that she had several fistulas, including some invasion of her bladder by the mesh. We completed our abdominal wall reconstruction with the Veritas Collagen Matrix and then applied the wound VAC.

During the case we talked about a couple other cases that we'll go through a slide presentation now to take a look at some of the experience that we've had with this product.

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To date we've had 28 cases that we've used in this particular application. We've had four recurrences in that time period, and they've occurred at about six months to one year. These recurrences have mainly been related to placement in the epigastric hernia position, which actually has a significant recurrence rate in the synthetic mesh application. In addition, we had one graft loss which we'll talk about in some of the subsequent slides. This first case that we're going to present is a 50-year-old gentleman who had a history of a colostomy with fascial dehiscence. He is a patient who has significant comorbidities, including peripheral vascular disease and a recent coronary artery bypass grafting. In

addition, he had a left hip disarticulation and now has a significant pressure sore and exposure of the sacrum and the iliac crest. He had a large contaminated wound requiring placement of a colostomy, however, developed a significant abdominal defect.

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As you see in this picture on the right side of the screen -- pardon me, on the left side of the screen, there is a large ventral defect extending almost the entire length of his abdomen and he has an ostomy towards the left side of his abdomen. We did use one piece of the Veritas Collage Matrix to reconstruct his abdominal wall. This was a markedly contaminated wound, and after irrigation with antibiotic saline solution, we were able to place the Veritas into position. And we did this in a similar fashion as we had just done on the case you'd seen using the 2-0 Prolene suture in a running fashion. This patient did have an application of the wound VAC as previously mentioned. And you can see the finished product after it's been placed. We did this as an interposition graft, and that's the wound VAC. Wound VACs serve multiple purposes here: one, to hasten the regeneration or modeling period. In addition, it also was able to isolate our wound from the colostomy, which aided in its healing. This is the patient after probably about two to two and a half months. The patient has almost had complete resolution of his midline wound and actually had just a small area that later required a skin graft. You can see he's actually healed quite nicely despite his poor nutritional status.

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Our second case here is actually a patient, 56-year-old gentlemen with severe necrotizing pancreatitis requiring multiple necrosectomies as well as bowel resection. This patient also, like many of our patients, has significant comorbidities, including myocardial disease, myocardial infarction, and also a history of hypertension. His defect size, as you can see, was quite large, about 20 x 14 centimeters, which was common in this area. And now with - - we have the larger sizes in the Veritas Matrix and we're not just limited to the smaller sheets which we have to patchwork, we actually have a 12 x 25 that we can use. This was actually repaired with two pieces that were sutured together and secured with an 0 Prolene suture. You can see on this patient he has a significant amount of subcutaneous fat, and you can see the pseudomonas infection that had actually been present. At this point in time he's been treated with both antibiotics as well as open wound irrigation and now is ready for application of his Veritas. This is the patchwork that we talked about during the case, which in most cases we didn't have to utilize any more with the larger pieces. Once again, this is a very easy product to sew in, it's a very easy product for the nursing staff and the operating staff to handle. There's no rehydration period here. The material holds suture very well. I have not in the 28 cases had any dehiscence due to suture failure. This is the product after it had actually been granulating, and the patient had actually good granulation tissue. Unfortunately, he did ultimately die from his disease process but actually had a very good healing wound bed despite his poor clinical course. And you can see the dramatic granulation tissue within this wound. You can already see the wound starting to contract with application of the wound VAC. This wound took approximately four weeks to get to this level, but this was in a patient who was severely malnourished with very low serum albumin levels and also an ongoing sepsis.

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Our third case here is one of the most dramatic cases we've had with the Veritas product. This is a 22-year-old female who actually developed necrotizing pancreatitis due to hyperlipidemia. She had an interpositional Veritas placed. As you can see, the wound defect was approximately 16 x 10 centimeters. She initially had placement of the Veritas product in the face of severe contamination, and the wound VAC was applied to it; however, we did have loss of the product within approximately 48 to 72 hours. This patient had severe intraabdominal pseudomonas that was causing this necrosis, therefore, she underwent multiple surgeries for debride of her pancreas and also intraabdominal washouts. And ultimately, we were able to close her with a quilted piece of the Veritas products. This was

done in a similar running fashion using the Prolene suture as well as the quilt work was done using Prolene suture. The wound VAC was applied and the patient had a dramatic recovery. She is actually having her first baby within the next several weeks and has had not significant problems during her pregnancy with abdominal hernias or recurrence.

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Another patient of ours is a 51-year-old male who had a history of diverticulitis complicated by abdominal wall dehiscence and multiple abdominal wall procedures for small bowel obstruction. He came to us with a very large ventral hernia that was in that Swiss cheese type pattern and required excision of this abdominal wall defect. We did utilize component separation, which is another area that we can actually use Veritas either to repair our lateral defects used in the component separation to allow us to approximate the midline and then we also did use it as an onlay on top of the repair. And as you see, this midline wound is actually repaired. We were able to primarily close them utilizing bilateral component separation. He did have primary wound closure. Postoperatively he developed a [pseuroma] approximately two weeks into his course. This was drained and without complication, and the patient actually continues to do well. I've seen him in follow-up now within the last -- approximately a year and a half out from his initial repair, and he's got a very good, sturdy repair with no evidence of recurrence. You can see the onlay portion of the mesh, and what we actually did is sew this circumferentially around the periphery using an absorbable suture, and within the midline there we actually use an absorbable suture to anchor it to the underlying fascial closure to prevent any fluid accumulating underneath the product not allowing it to regenerate or remodel.

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One of our last patients here is an 82-year-old female who had had multiple ventral hernia repairs and actually had a Kugel mesh placed for her final repair and developed drainage near the umbilicus. Her comorbidities, astoundingly at age 82, were only hypertension and diabetes, which was well controlled. She had approximately a 15 x 8 centimeter defect with a fistula within the defect requiring repair of the small bowel and underwent placement of Veritas in an inlay. And as we talked about during the case, you can actually do the repair either utilizing an underlay technique or an inlay technique. I would not recommend placing this in an onlay without primary closure underneath. I do put it in interpositional position due to the fact that I think we get -- in terms of regeneration of tissue, I think it provides for a better matrix or a better mattress for this to occur, as opposed to the underlay technique, which may be abutting the peritoneum. You see here, this is -- the clamp actually is at the umbilicus, where a fistula was protruding through. She had significant contracture of the mesh, which you don't see in this biologic product. This biologic product, Veritas, will actually have some laxity but not enough to cause any significant evidence of a hernia as seen by the patient. This mesh had contracted to approximately a third of its size, and the fistula was actually emanating through the middle of it. This is just a picture at the top portion of the specimen there. You can see that there's some mesh that it's actually contracted. I believe this was approximately a 10-centimeter round piece of mesh. We did this, as I said, in an interpositional position and had the VAC placed in the operating room. I think this is a key component for multiple reasons: one, for as we talked about, to hasten that regeneration and remodeling process, and two, I think it also aids in the hemostasis of these large flaps that we create by suturing -- by developing those flaps around the fascia.

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So using this Veritas product I think is important in these kind of cases. Veritas being the collagen matrix that's not cross-linked allows us to use this in a contaminated setting. I think it's important in these kind of difficult abdominal wall reconstructions that we do have products outside of the synthetic mesh realm and that case that we presented today would not be possible to repair with a mesh product due to the fact that she had contamination with both yeast as well as the MRSA that everybody fears. Using this product, I feel comfortable that this patient will not have any significant wound infection issues and will

hopefully have a long-term durable repair of this abdominal wall hernia. I would like to thank the SSM healthcare system and St. Mary's Health Center for allowing us to proceed with this case. I also would like to thank Synovis for the introduction of the Veritas product into this market. And I would like to thank my operating room staff and team for an excellent job. And you can note that this actually -- this presentation will be archived on the OR-Live website.

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ANNOUNCER: This has been a complex abdominal wall repair using Veritas Collagen Matrix performed from SSN St. Mary's Health Center in Richmond Heights, Missouri. OR-Live makes it easy for you to learn more. Just click on the "request information" button on your webcast screen and open the door to informed medical care. This even was sponsored by Synovis Life Technologies.

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