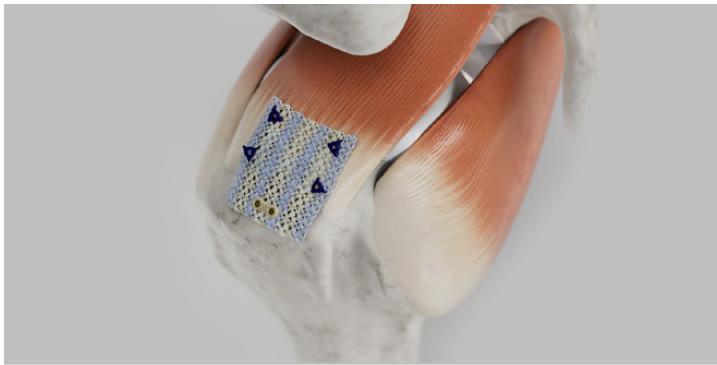


HA Powerhouse Anika Upending Orthopedics?

BY ROBIN YOUNG



From top left clockwise: Integrity® Rotator Cuff Scaffold; Cingal® HA + Triamcinolone Hexacetonide knee injection; RevoMotion™ and Anika CEO Cheryl R. Blanchard, Ph.D. / Courtesy of Anika Therapeutics, Inc.

Disruptive technologies tend to upend tradition-bound companies and industries.

Anika Therapeutics, Inc., the largest supplier of hyaluronic acid (one of the most slippery substances known to man) to treat knee pain and arthritis—a technology first brought to market in the 1950s—is launching, not one, not two, but three breakthrough orthopedic technologies.

With these three launches, Anika's addressable markets leap from \$1 billion to \$8 billion.

The Three Breakthrough Technologies are...

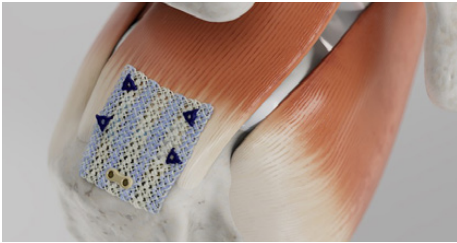
1. Next Generation Rotator Cuff Scaffold

- a. **Brand Name:** Integrity®
- b. **Technology:** 80% esterified hyaluronic acid fiber matrix combined with 20% non-resorbable polyethylene terephthalate (PET) fibers which forms a composite scaffold for cellular infiltration and new tissue growth.
- c. **Features:** Superior strength (holds sutures when hydrated), promotes tissue remodeling & regeneration, resorption, fixation, implantation, and instrumentation. Sup-

ported with a significant body of published literature.

- d. **Comments:** Anika CEO Cheryl R. Blanchard, Ph.D., explained the significance of Integrity to OTW: “We developed Integrity to address several unmet needs in rotator cuff pathologies and other soft tissue fixation markets. Strength, ease of implantation, regenerative profile, fixation, and instrumentation.”

“Current collagen-based rotator cuff patches are similar and different in various aspects, but they all have one thing in common—inadequate strength, especially when hydrated, which is what



Integrity® Rotator Cuff Scaffold

happens immediately upon implantation. Who cares how strong they are when they're in the box? It doesn't matter clinically. They also can't hold a suture."

"Integrity does all that and more. I walked around with an Integrity Implant patch in my pocket showing it to surgeons for two weeks. You know what the surgeons wanted to do? They want to try to rip it. I had one surgeon say, 'Can I try to destroy it?' I said, be my guest. After two weeks,

that patch was still in the same shape as it was when I took it out of the box. It also behaves that way when hydrated and maybe more importantly with sutures."

"We did a head-to-head animal study against the current #1 selling rotator cuff patch and Integrity showed about three times the regenerative capacity. It resulted in organized and much thicker repair tissue. The fibers in Integrity are aligned and organized, but they are also interdigitating with the original tendon and forming a new repair tendon."

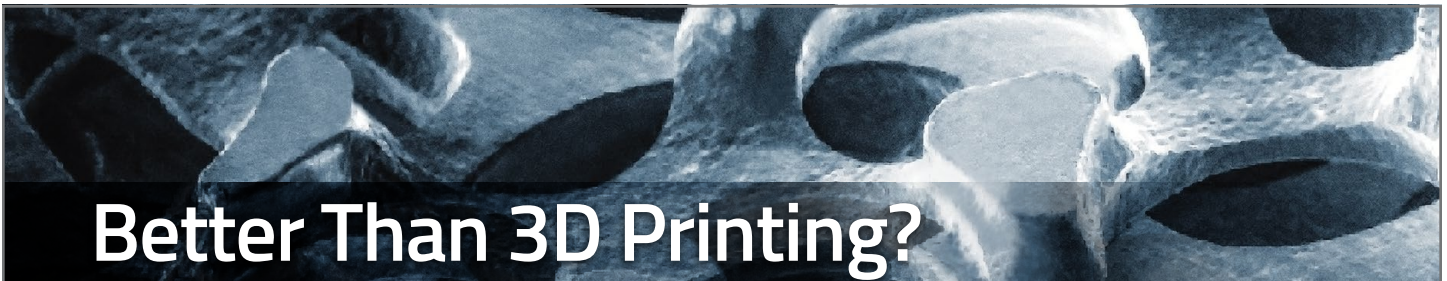
"The histology is beautiful. Integrity can immediately be used in the shoulder, foot and ankle, hip, and knee. It's on label for augmenting tendon repair."

2. Next Generation Injection to Treat Knee Pain and Arthritis

a. Brand Name: Cingal

b. Technology: 88mg of high molecular weight, cross-linked, viscous HA combined with triamcinolone hexacetonide (TH) steroid.

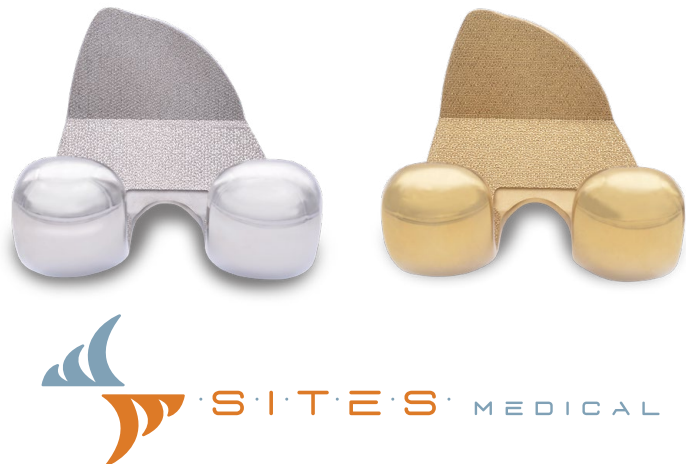
c. Features: Extended residence time in the knee, rapid action pain relief and longer lasting pain relief, binds well with water forming highly viscous polymers that increase the ability of native synovial fluid to cushion the knee joint and absorb shocks. Product has been available in 35 countries—not the USA—for years. A



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Cingal® HA + triamcinolone hexacetonide knee injection

significant body of literature is available.

A 2013 study tested Cingal against HA alone and saline. The study was a multicenter, double-blind, saline-controlled clinical trial where patients were randomized to

one of three arms—saline, HA, or Cingal.

Three hundred sixty-eight patients were enrolled. After injection, patients' pain levels were measured using the WOMAC (Western Ontario and McMaster Universities

Arthritis Index) Pain Score through 12 weeks. In addition, the research teams conducted Patient and Evaluator Global Assessments, OMERACT-OARSI Responder index, and WOMAC Total, Stiffness, and Physical Function scores through 26 weeks.

How did the patients respond to Cingal, HA and saline?

The 149 patients receiving Cingal reported 70% pain reduction at 12 weeks, 72% at 26 weeks with 92% OMERACT-OARSI responders. That was significantly better than the 69 patients who were treated with saline AND the 150 patients treated with HA alone.

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According to the research team: “Cingal provides immediate and long-term relief of osteoarthritis-related pain, stiffness, and function, significant through 26 weeks compared to saline. Cingal showed significant early pain relief compared to HA alone, while maintaining long-term pain relief comparable to HA through 26 weeks.

A 2017 study tested Cingal against TH steroid alone and saline placebo. The study was a multicenter, double-blind, saline-controlled clinical trial where patients were randomized to one of three arms—saline, TH, or Cingal. Two hundred thirty-four patients were enrolled, and the same measures were used as in the 2013 study. This study demonstrated superiority of Cingal over TH at 26 weeks with the same strong performance for pain and responder rate as in the 2013 study.

d. Comments: When OTW mentioned Cingal to Anika CEO Cheryl Blanchard, her eyes lit up and said, “That’s my favorite product and the data is unparalleled.”

Dr. Blanchard continued, “Anika has been selling Cingal in over 35 countries for many years. It is a double-digit growth driver for our company and it’s a product that continues to gain adoption alongside MONOVISC. It is complimentary in that it doesn’t cannibalize MONOVISC, which is a common

question that I hear. What it does replace is corticosteroid injections.”

“Typically, steroids are prescribed first, before an HA injection. In the countries where we are marketing Cingal, it has been growing alongside our flagship HA product MONOVISC and replaces the traditional corticosteroid injections.”

“I speak with the clinicians that use it often. Cingal has the best data out there in terms of pain relief and responder rates. It is the only product in large randomized clinical trials that has now shown superiority to two active ingredients. Nobody and no product have done this before.”

“We have a product that is superior to its two active ingredients—triamcinolone hexacetonide and HA. It’s a special product and one that has been studied now in three phase three clinical trials.”

“We announced that we have met with the FDA and are waiting for their feedback on a proposal they asked us to submit. We have met the clinical endpoints that FDA requested—namely superiority to the two active ingredients.”

“We would be more bullish than ever with Cingal approved in the United States.”

3. Smallest Diameter Glenoid Base Plate for Reverse Shoulder Arthroplasty

a. Brand Name: RevoMotion™

b. Technology: At 23mm, this is the industry’s smallest diameter threaded glenoid baseplate for reverse shoulder arthroplasty. Its design also includes a curved-back with 4mm of lateralization from the glenoid face, a 6.5mm center screw and a glenosphere insertion slot with a unique coupling between baseplate and center screw. All of these details lead to restoration of the Gothic Arch.

c. Features: Smallest profile, designed to reduce scapular notching and more impingement-free range of motion for the patient. Ten times the compressive force of a center post baseplate. And because of the design of the insertion slot and baseplate coupling with the center screw, assembly and insertion is easier.

d. Comments: The market for reverse shoulder arthroplasty is crowded with much larger players like Stryker, Zimmer or DePuy. Anika’s key differentiation is the smaller profile—which is highly significant since it directly affects the patient’s eventual shoulder range of motion. Anika then incorporated other design aspects to also increase post-op patient range of motion and ease of use for the surgeon.

Anika CEO Cheryl Blanchard told OTW, “RevoMotion is an amazing product for reverse total shoulder arthroplasty.

The shoulder arthroplasty market has shifted more and more to the reverse approach.”

“Surgeons don't like to do an anatomic shoulder arthroplasty unless there's a reverse backup in the OR and they don't like to call two reps into the operating room from competing organizations. Our Arthrosurface joint line based on its bone preserving attributes and the RevoMotion, it has the smallest threaded glenoid baseplate, which, by the way surgeons are really excited about—it gives them options about where to place it in the glenoid—very anatomic and they love the two-instrument tray system optimized for the ASC.”

“It's popular in the ASC and provides Anika the ability to infiltrate the other 80% of the market with a true continuum of care for glenohumeral osteoarthritis and rotator cuff solutions alongside RevoMotion.”

“We're actively training surgeons and I'm receiving amazing feedback from them. Beautiful X-rays which visually show how our designs translate into form and function. Our early patients are almost a year out now, they're doing great, and some have even come back saying please put it on the other side.”

“We know RevoMotion is a spectacular product that will positively impact surgeons and patients alike. Our happiest patients with our Arthrosurface

shoulder line including our OvoMotion anatomic shoulder thus far are weightlifters—a most demanding patient population who do not want to be limited in activity, but it's even more appropriate and exciting for those patients who are less active, older, and who just want to live their daily lives without pain.

Anika Therapeutics Circa 2024

To paraphrase an old business maxim: if you don't kill your own favorite products, your competitors will.

Under CEO Blanchard, a former senior Zimmer executive, Anika has indeed attempted to disrupt itself—although, notably with Cingal, not affected by its flagship Monovisc®, instead, taking share from traditional corticosteroids.

For details of this remarkable journey, see OTW's article: [“The Improbable Transformation of Anika Therapeutics.”](#)

With three significant new technologies launching in 2023-2024 and more in 2025, Anika's sales are likely to accelerate significantly—perhaps attracting strategic interest in the process. As we noted at the start of this article, these new technologies expand Anika's addressable market to \$8 billion.

Wall Street is valuing Anika at about \$300

million and expects that sales in 2024 will increase 9% to \$175 million. To put that in perspective, Anika's sales growth was 5% in 2022 and 6% for the nine months ended September 2023.

At \$300 million in market value, Anika is trading at 1.7x expected 2024 sales while the average orthopedic company is trading at 4.33x sales. Anika is reporting losses (about \$20 million as of the nine-months ending in September), which probably explains why Wall Street is keeping Anika's valuation at modest levels. Anika, however, has no long-term debt and about \$70 million in cash.

In orthopedics today, there is probably not a more fascinating company than Anika Therapeutics. This management team, led by Cheryl R. Blanchard, Ph.D., is thinking big and creatively while staying laser focused on clinically documented patient improvement and surgeon empowerment.

Stay tuned, for sure. ♦



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