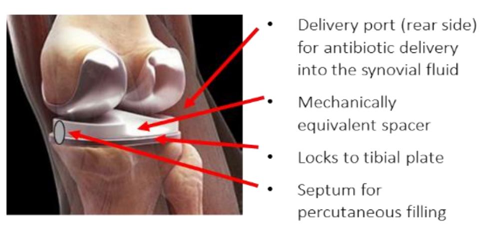
ForCast Orthopedics, Executive Summary

While the total-knee replacement market is large, $18B, > 1.4M procedures (2016), these patients risk periprosthetic joint infection (PJI). PJI rates range from 0.5-5.0% as acute, chronic or latent, e.g., after multiple years. Over 74,000 global PJI cases were estimated for 2017.

Current PJI treatment options are poor: all are surgical; all have a low/limited effectivity (averages 55-90%); have significant patient morbidity; and costly ($55k to $163k per patient). Current standard-of-care options (e.g., I&D/PE exchange, 1-Stage or 2-Stage Revisions) do not address the need for consistent, therapeutic antibiotic levels in the knee's synovial fluid during the treatment. Conversely, ***managing synovial fluid antibiotic concentrations is a proven method for PJI eradication, documented in clinical research***[1]. Unfortunately, this research method requires daily antibiotic injections through indwelling catheters, undermining broad clinical adoption.

We're leveraging this proven therapeutic approach but implementing a solution that minimizes patient and provider burden. Our proprietary ACE Knee Spacer™ uniquely provides direct, intra-articular antibiotic infusion, maintaining therapeutic levels during treatment, thereby projecting improved outcomes and lower costs. Of course, outcomes are dependent upon other surgical factors (e.g., thorough debridement, etc.) that must be addressed as part of the total solution. ACE Knee Spacer represents the first opportunity to maintain therapeutic antibiotic levels in the knee's synovial fluid over a continuous treatment period of 6 weeks to 6 months, if necessary. Further, with its fill/refill capability as a combination drug/delivery device, the physician can select an antibiotic targeted to the bacterial infection diagnosed.



Our proprietary ACE Knee Spacer uses an internal reservoir and infusion system for intra-knee antibiotic delivery for up to 9 days, by/before which patients return for a weekly office evaluation and simple percutaneous needle injection for refilling. ***When antibiotic treatment is complete, the empty spacer is left in place – a unique benefit***. As a permanent spacer, fully compliant with FDA, ISO and ASTM requirements, the ACE Knee Spacer ***eliminates the need for a second, replacement surgery***. This can save as much as $63,000/patient in hospital/therapy costs. The ACE spacer is a "smart implant." It also provides a vehicle for precision delivery of other liquid medication therapies, e.g., prophylactic antibiotics (primary), steroids, analgesics, hyaluronic acid, stem-therapies, etc.

We: * understand the regulatory pathway with industry leading experts; * have foundational intellectual property (US 9,839,523) + additional applications; * have initial interest from potential strategic partners; * are building an SAB of renowned orthopedic surgeons; and * have strong leadership comprised of an orthopedic surgeon/inventor and experienced met-tech executive. For additional information regarding investment opportunities, please contact us below:

Jeff Castleberry, CEO, President & Co-Founder
ForCast Orthopedics
jcastleberry@forcastortho.com
303-503-4818

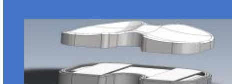
www.forcastortho.com

PJI is devastating to patient health, frustrating to surgeons, and costly

$315M WW market for PJI treatment, $1.6B market when integrated into existing knee implants prophylactically

Addresses value-based pricing pressure on patient outcomes

ACE Knee Spacer can eliminate the need for a 2nd surgery



ACE Knee Spacer

1. Reprints of study articles are available