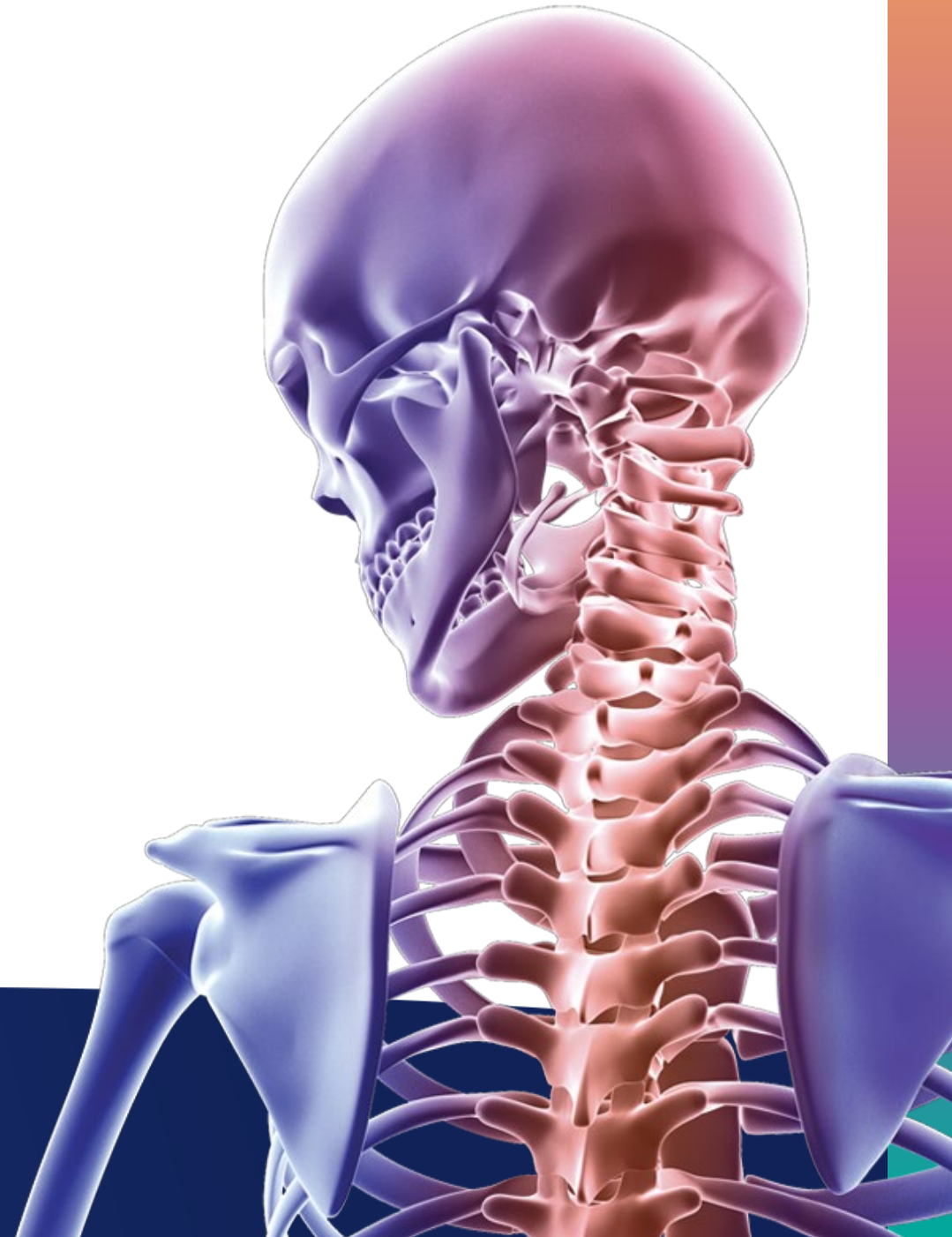


Advanced Additive Manufacturing Takes Engineering to the Next Level

Matthew Shomper, Not a Robot Engineering

Alyssa Huffman, Allumin8



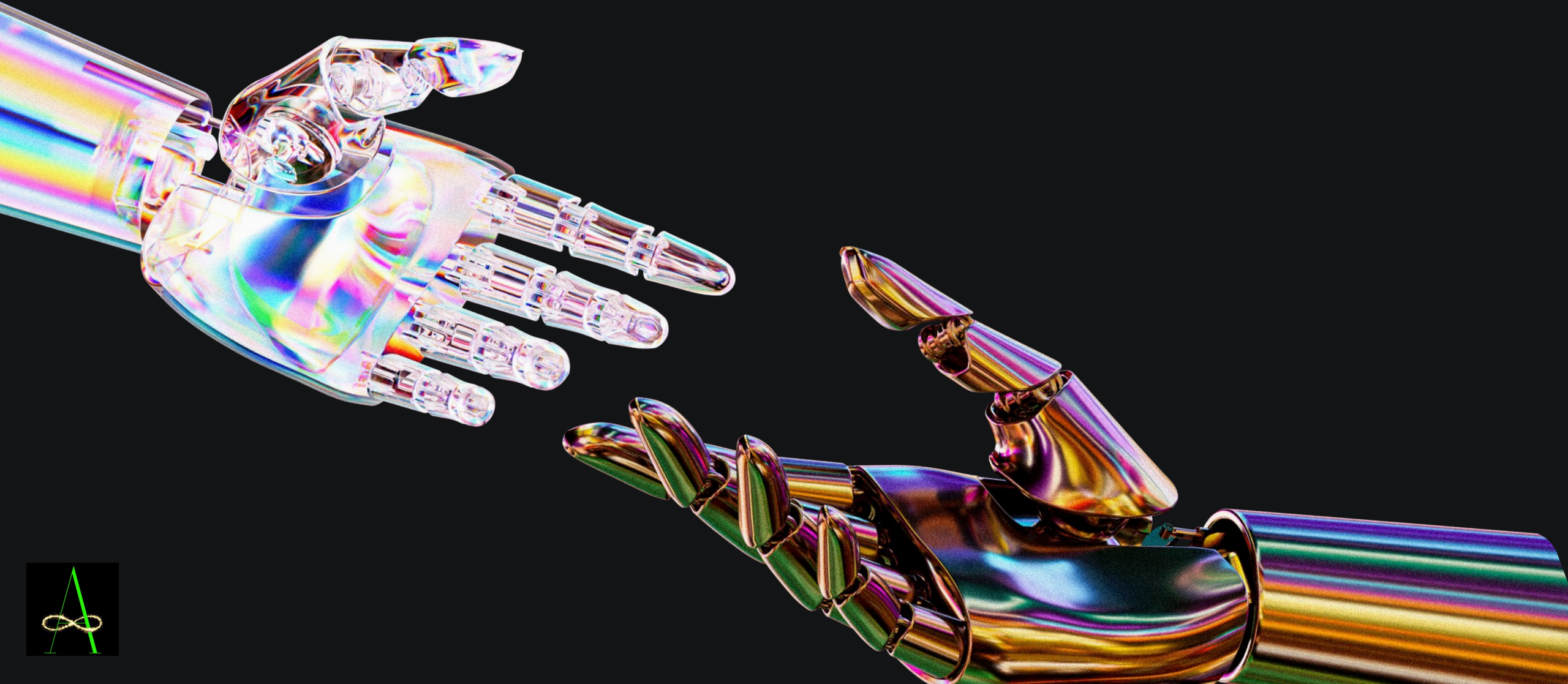
Advanced Additive Manufacturing Takes Engineering to the Next Level.



Matt Shomper - CTO

Alyssa Huffman - CEO

Let's Design Utopia Together...



“Bone is a living tissue. It’s not enough to put in a static implant that doesn’t respond to bone remodeling,” she said. “Implants are needed for mechanical support. We’ve made changes to the implant topography and pore size, and that’s helping, but we still need a biological stimulus. That’s why I believe it’s not one versus the other.”

Dr Zorica Buser



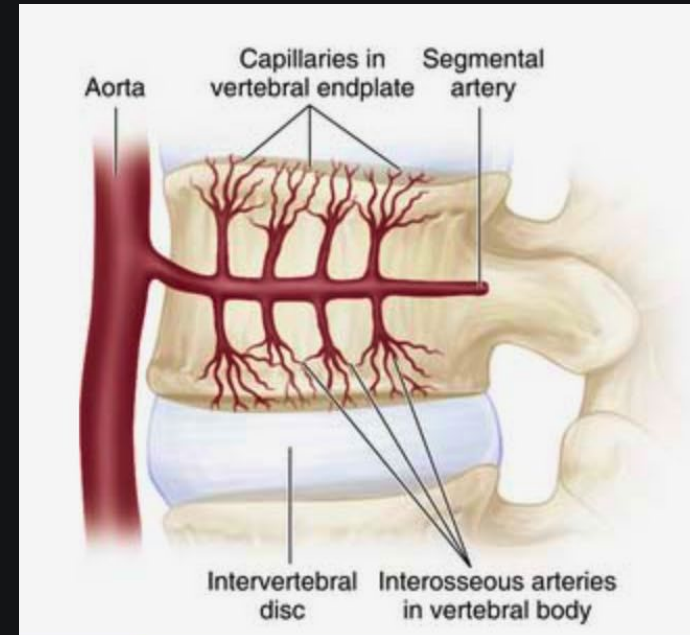
Basics About the Body

- ICD-11 recognizes up to 300 unique bone diseases and disorders
- Many diseases act concurrently
- Over time infections and cancer can mutate
- Inflammation impedes healing
- Bone has vascular variables (delivering nutrients is not fully understood)



Basics of Bone

- Likes trabecular patterns
- 3D printing is the fastest and most cost effective approach to achieving these patterns
- Bone patterns & density are different throughout the body
- Blood supply and nutrient delivery is different throughout the body
- Women and men heal from fracture differently



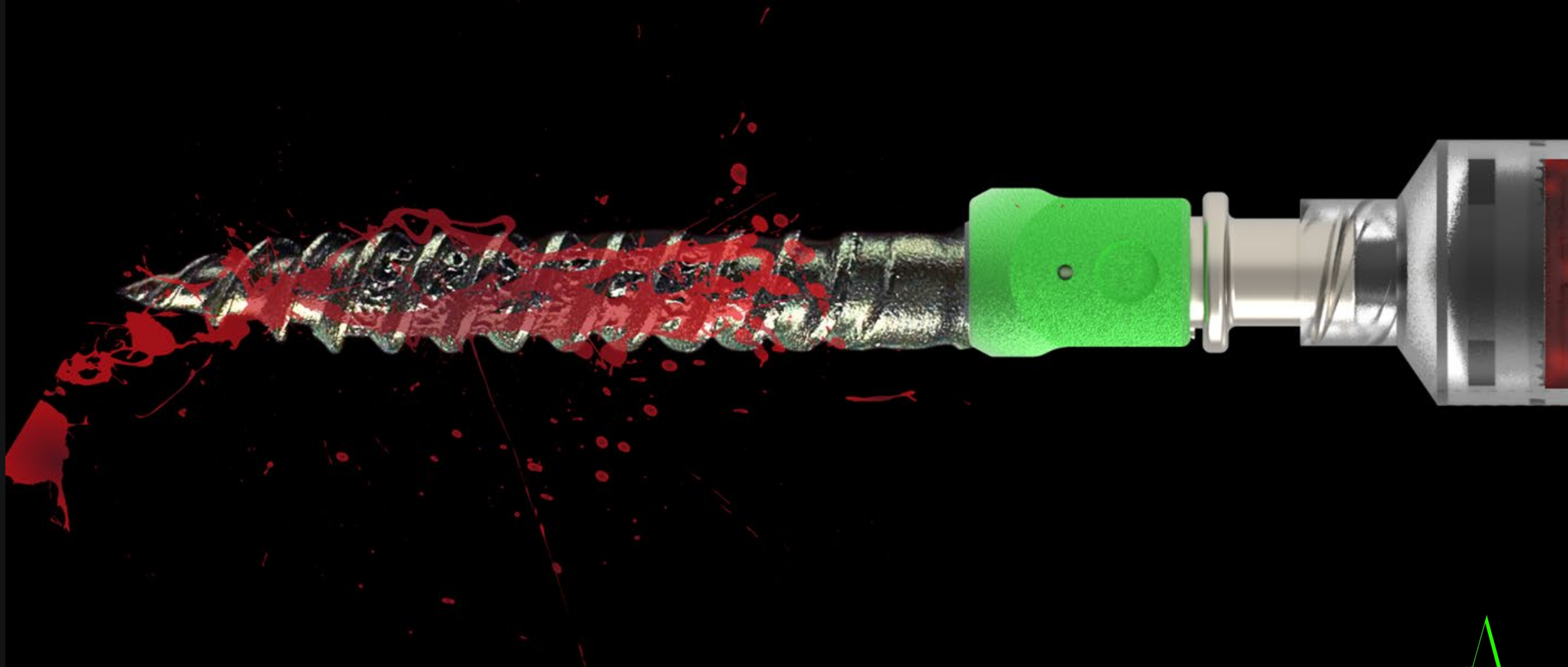
What Does the Perfect Product Do?

- Works in all hands/training philosophies
- Does not fail (ex: total hip replacements - 96% survivorship)
- More than 10% better outcomes than the gold standard
- Does not create an additional problem (ex: osteolysis/infection/etc.)
- Not too expensive
- FDA predictable pathway
- Reimbursement pathway
- Can gain adoption quickly (not too future forward)
- Doesn't rely on patient creating new habits
- Does not disrupt workflow (new technique, office modifications, requires CT/MRI for customization, delays surgery)





WORLDS FIRST BIO-LOGICAL DELIVERY HARDWARE



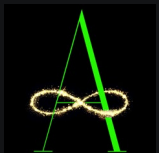
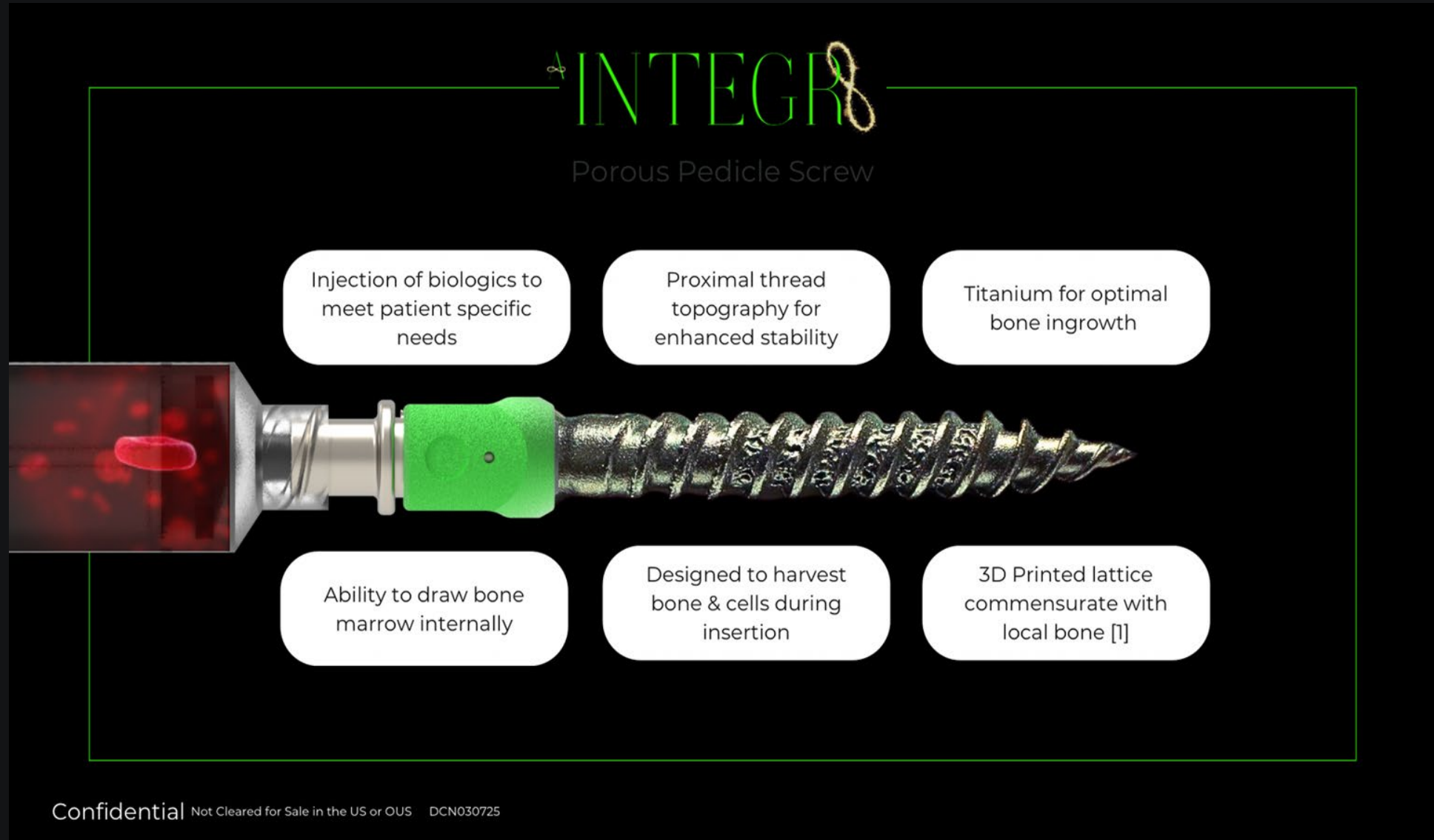
Confidential Not Cleared for Sale in the US or OUS DCN050125



Why We Called Matt... FAILURES



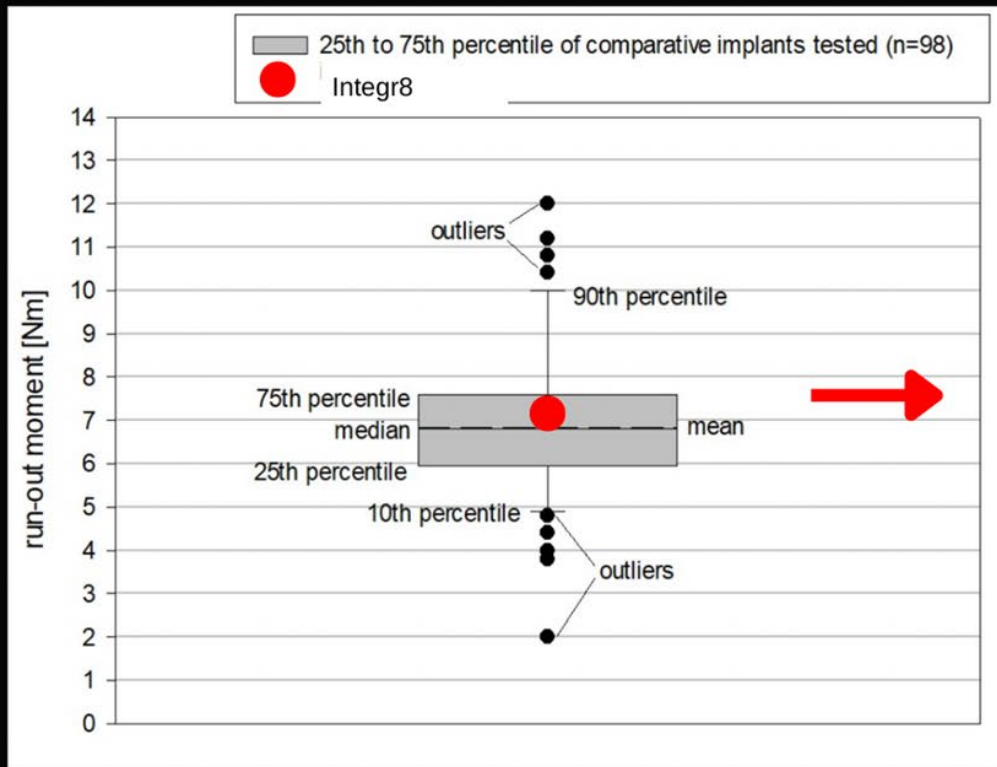
What We Created...



What We Created...



510K SUBMISSION DATA



- Successfully completed ASTM1717 5MM cycles of static & dynamic testing **46% higher load (175N)**
- **Stronger** than over 50% of screws in **DYNAMIC** testing
- **Stronger** than over 90% of screws in **STATIC** testing



What We Created...



A8's Why...



Case Study 1:

What would benefit a 20-year-old female with incomplete quadriplegia?

How are pediatrics different?



Case Study 1:

What are the most inherent risks?

- Screw loosening
- Infection
- DVT
- Altered load patterns
- Compromised wound healing
- Reduced pain perception
- Nutritional deficiencies



Case Study 2:

What would benefit a 74-year-old male diabetic, MRSA carrier with loose screws, open wounds who's on his sixth revision?



Case Study 2:

What are the most inherent risks?

- Infection and sepsis
- Hardware failure & poor fixation
- Delayed or nonunion (pseudarthrosis)
- Wound healing complications
- Neurological injury
- Blood loss & anemia
- DVT/PE
- Prolonged hospitalization
- Reduced functional outcome



Case Study 3:

What would benefit a 74-year-old male diabetic with history of b-cell/large cell lymphoma mutations and 93% most aggressive prostate cancer?



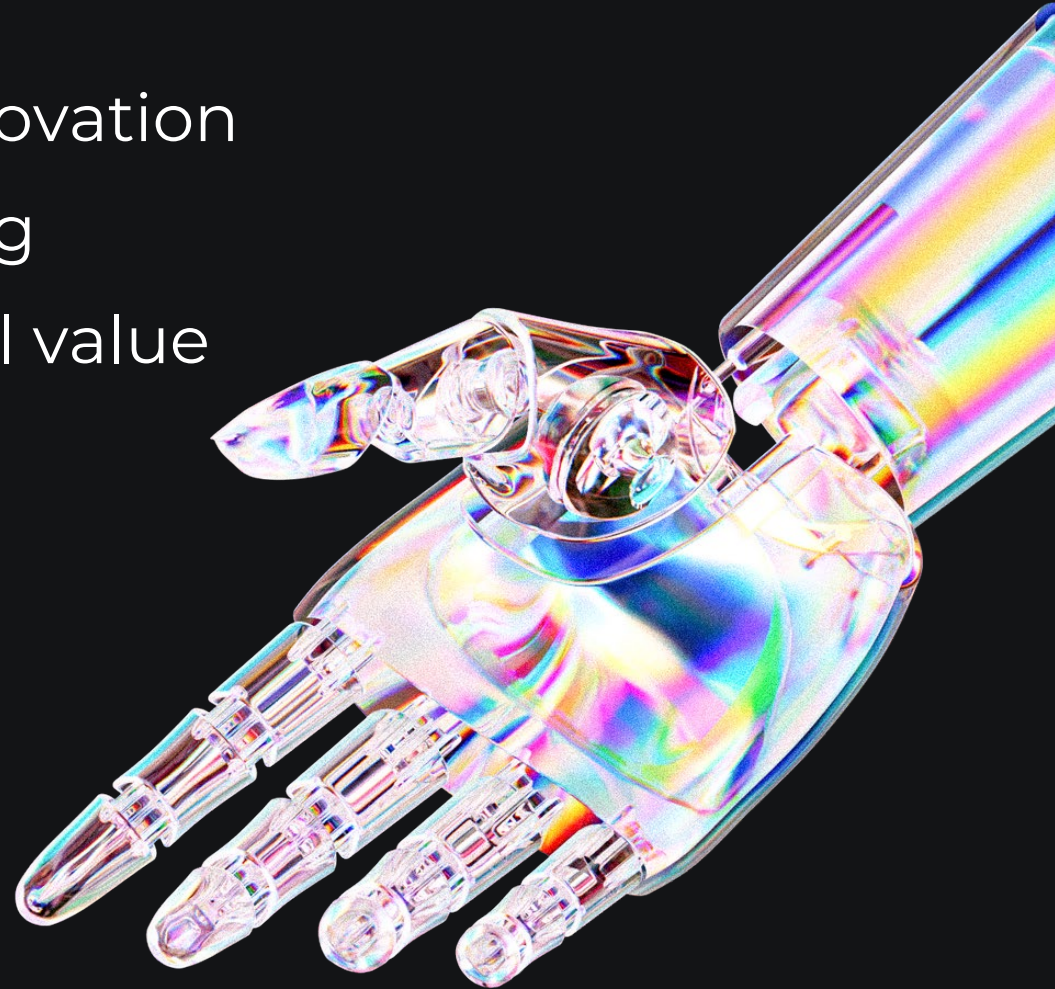
What Does the Future Offer?

- Slow and targeted small molecules delivering therapeutics over predictable time frames
- Treating concurrent disease states
- AI dictating the most effective combination of small molecules to mix in a syringe with hydrogels/bioinks and inject intraoperatively
- Future biologic delivery to treat or stabilize
- Nutrient delivery
- Biomechanical functionality meets precision medicine
- Societal demand to push Regulatory to clear
- Longevity extension for implants



Striving for Outcomes (>25%)

- Better patient outcomes = true innovation
- Justify years of dedication & funding
- Avoid 'Me Too' trap with real clinical value
- Make the risk worth the reward



Let's Make it Meaningful.





Thank you!

EMAIL

matt@allumin8.com
alyssa@allumin8.com

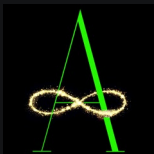
WEBSITE

allumin8.com

Navigating Regulatory Realities

- FDA outcomes are unpredictable
- Reviewer changes = timeline changes
- PMA pathway is costly and slow
- Perception > data in early reviews
- Risk aversion leads to 'Me Too' products

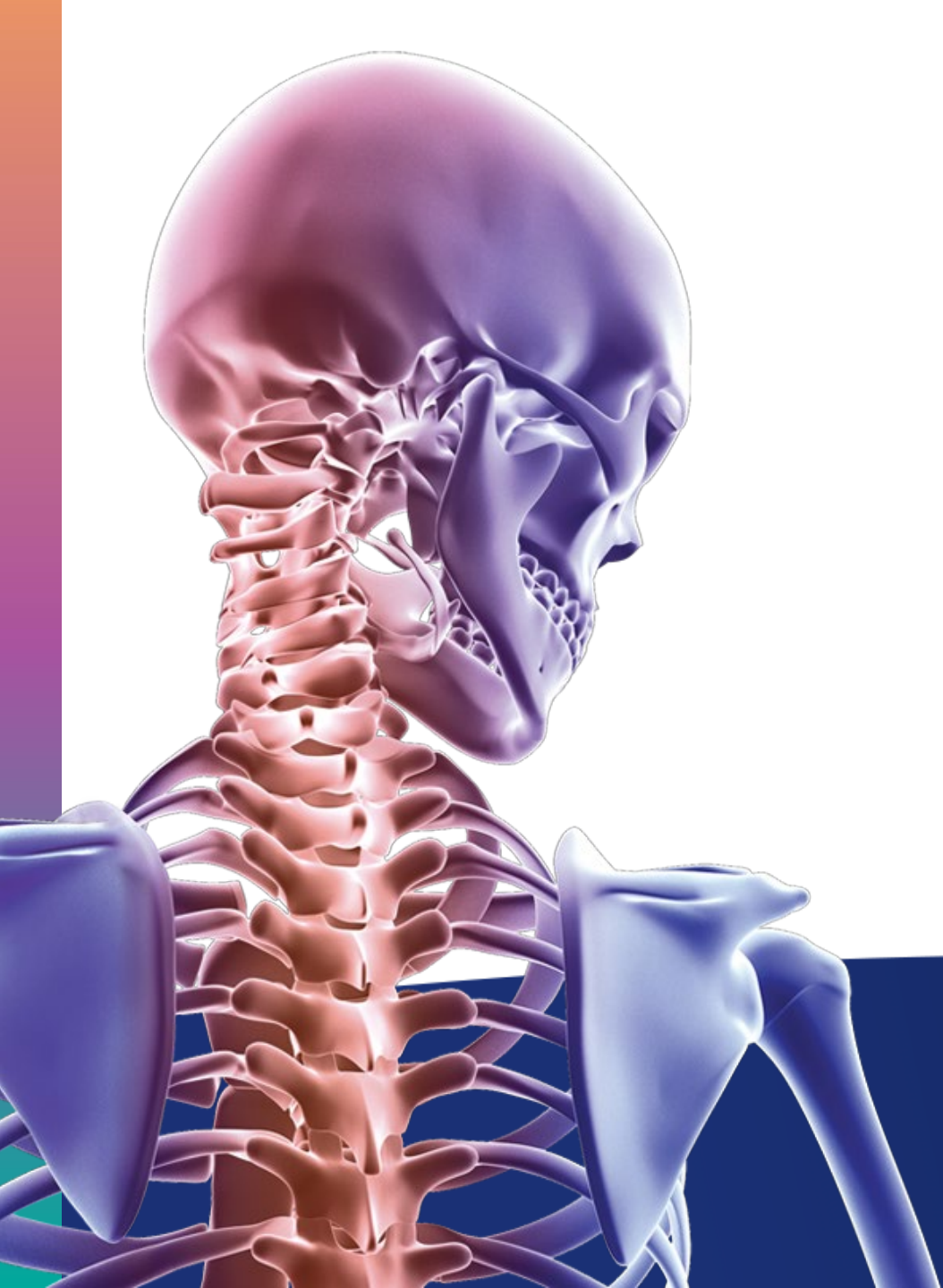
IS IT SAFE?



Will it sell?

- Bypass exclusivity agreements
- Significant improvement over competitive products
- Meets hospital needs (infection/readmission/etc.)
- Gain Value Analysis approval
- Can sales understand & deliver the messaging?
- Can the practitioner understand it?





Thank You for Attending!

**We value your feedback.
Please fill out a session evaluation
before you leave.**