Orthopedic Smart Devices

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Welcome & Thank You!

FDA
Industry
Clinicians
Academia
Remote Attendees

Session Goal:
Open dialogue discussing landscape of SMART Technologies:
• How they are utilized?
• Future technology uses – what’s next?
• What are the regulatory considerations in the future to support this innovation?
Following years of successful innovation, variability in outcomes still exists...

13% 5-yr mal-fusion/re-surgery rate
20-40% rate of failed back surgery syndrome (FBSS) post surgery

4-5% 10 year revision rate and >2x outcome difference between high & low volume centers (transfusion, infection, patient satisfaction)

“Less Experienced” surgeons take 30 minutes longer, make up 50% of volume, are 2x more likely to get poorer outcomes and are open to adopting technology.
We have traditionally sought to improve outcomes through implant design...
But we know there are factors beyond the implant, both outside & inside the OR which influence outcomes...
And every patient is unique with a different set of goals. How do we improve Patient Desired Outcomes?
Technology will play an Expanding Role in Healthcare
Quite literally “all around” us

Outside the OR

- Smart Ring
- Smart Glasses
- Smart Finger
- Smart Bracelet
- Smart Belt
- Smart Pants
- Smart Socks
- Smart Watch
- Bluetooth Key Tracker
- Smart Shirt

Inside the OR

- Video Report
  - Time-stamped comments
  - Postoperative assessment
  - Relative movements of performed elements

Surgical Process Institute

Johnson & Johnson - Medical Devices
SMART Technologies Will Enable a New Paradigm in Defining Success

Connecting these devices across the continuum will deliver significant amounts of meaningful data.
Data Can Help us Measure and Redefine Outcomes

*Can it also lead to new product claims?*

“Can I pick up my grandkids?”

“Will I ever run a marathon again?”

“Can I confidently take the stairs?”

**What is success?**

Radiographic Fusion

F/E Films

ODI

SF36

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**Patient Desired Outcomes and Potential Product Claims?**

- Faster Recovery
- Return to Exercise
- Return to Daily Activities
- Return to Work
- Overall Satisfaction
SMART Technologies Will Enable a New Paradigm in Defining Success

Connecting these devices across the continuum will deliver significant amounts of meaningful data

Pre-Surgery Intra-op Post-Op Patient Monitoring

Data to drive outcomes

Patient reported factors

Patient behavior

Adherence

Patient Engagement

Physiological measurements

Activity levels

How was the procedure performed?

Loading

Balance

Sizing

Motion Assessment

Fusion Assessment

Rehabilitation Protocols

Telemedicine

Patient Engagement

Therapy Delivery

Physiological measurements

Activity levels

Caution:

Inclusion of consumer grade devices may impair our ability to draw the right conclusions.

These devices may not be optimizing to the same medical device standards.
Collection and PROTECTION of Patient Data is a Must

Watch outs are real and being tested every day

We should all be encouraging this, but we need to make sure they are appropriately regulated.

Protection of patient related data is critical to building and maintaining trust, particularly in the healthcare environment.

Cybersecurity protections must be in place to safeguard patients and ensure data is not compromised.

Collecting patient data comes with a responsibility. We must not allow ourselves to be consumed by “data overload” and instead focus our efforts on collecting only the relevant and meaningful data which will ADD value, and drive outcomes.
We have the Opportunity to Change the Trajectory of Healthcare

*Smart tech opens up new perspectives*

- We have opportunities today to leverage technologies and to link *meaningful* data across the continuum of care
- In doing so, we can improve outcomes AND broaden our definition of success & outcomes
- But we should be cautious, just because a device today may be widely utilized (eg fitness tracker), doesn’t mean it should help define the standard of care
- Data security is paramount
- Collaboration between FDA, Industry, Healthcare Providers, Academia will be required to support us on this journey
# Engineering and Technology Considerations Session

**SMART Technologies’ Role in Orthopaedics – Present and Future**

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<th>Time</th>
<th>Session</th>
<th>Presenter</th>
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<tr>
<td>8:45am</td>
<td>Current Landscape of SMART Technology in Orthopaedics</td>
<td>Mark Allen, PhD (University of Pennsylvania)</td>
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<td>9:00am</td>
<td>Utilization of SMART Technology: Passive Monitoring, Diagnostics, Automated Treatment</td>
<td>Shuvo Roy, PhD (University of California, San Francisco)</td>
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<td>9:15am</td>
<td>Industry Perspective on Market Considerations for SMART Technology</td>
<td>Lisa Ferrara, PhD (OrthoKinetic Technologies, LLC)</td>
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<td>9:30am</td>
<td>Future Applications for SMART Technology</td>
<td>Michel Maharbiz, PhD (University of California, Berkeley)</td>
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<td>9:45am</td>
<td>Panel Discussion</td>
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**Moderators:** Anton Dmitriev, PhD (FDA) and Vijay Goel, PhD (University of Toledo)