2025
WORK RELATED
Injuries Workshop

# Disruptive Technologies in Prosthetics

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# Disclosures

No financial disclosures

# Disruptive Technology

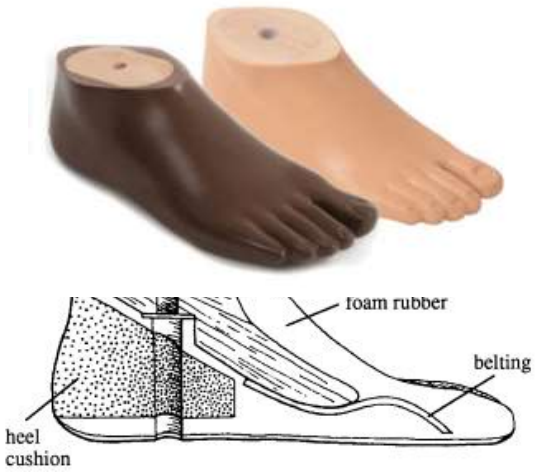
…is one that displaces an established technology and shakes up the industry or a ground-breaking product

# Disruptive Technology: Communication


# Disruptive Technology: Transportation

# Disruptive Technology: Entertainment

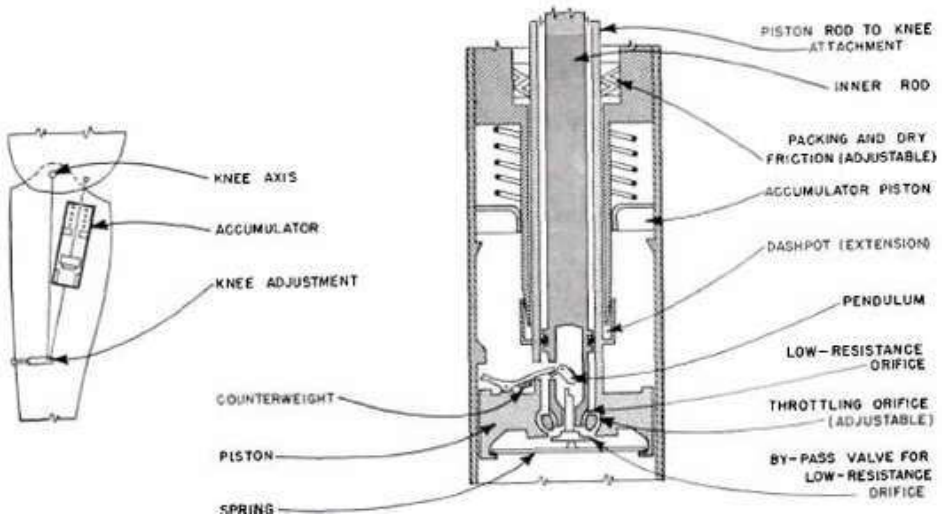

# Disruptive Technology: Prosthetic Feet




**1957: SACH Foot**

**1984: FlexFoot**

# Disruptive Technology: Prosthetic Knees




**1946: Mauch Hydraulic Knee**

**1997: C-Leg "Computerized Leg"**

# AGENDA

- What are the current challenges in prosthetics that can limit the functional potential of someone living with limb loss?
- Introduction to Osseointegration, the Luke Arm and CoApt Pattern Recognition.
  - The indications and contraindications of these new technologies
  - Costs and frequency of replacement associated with each of these new technologies will be outlined in order to assist in setting reserves for prosthetics with these different styles.
- What's next?

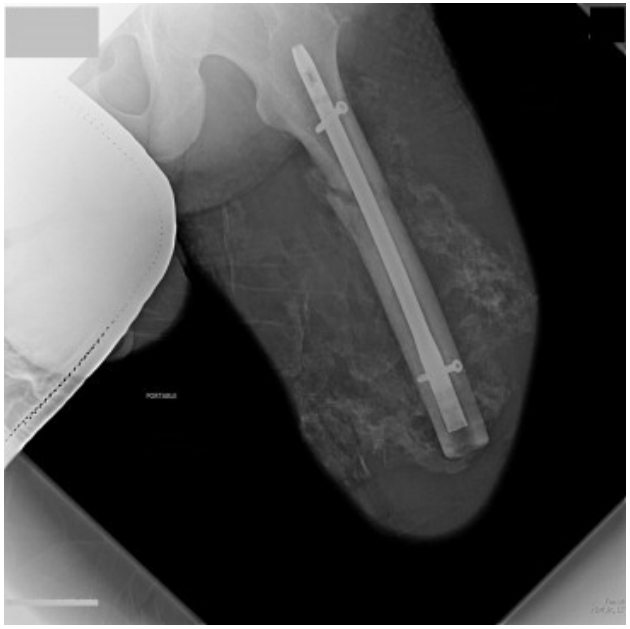
# Life without Limitations?

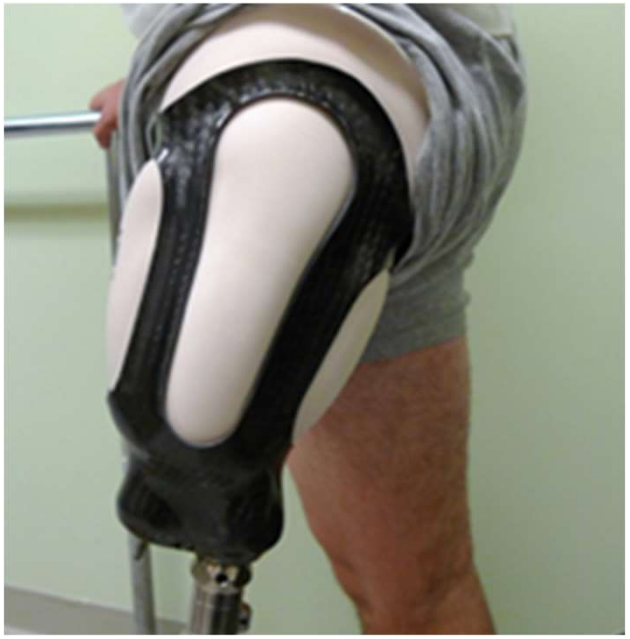
What are some of the challenges of living with limb loss and using a prosthesis?

# Socket

- Suspension
- Perspiration
- Hygiene
- Rotation
- Limb volume change

- CRPS
- Heterotopic Ossification (HO)
- Neuromas
- Bone Spurs
- Skill of prosthetist







# Limb Length and Multiple Amputations

# Durability

# Efficiency


One prosthesis for all activities

Responsiveness/natural movement

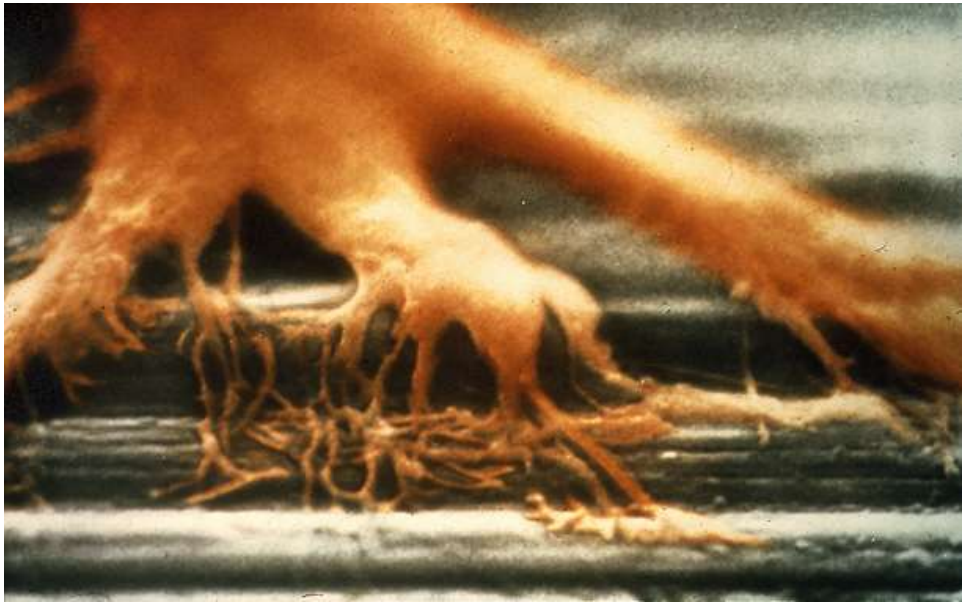
Normalized gait

# Osseointegration

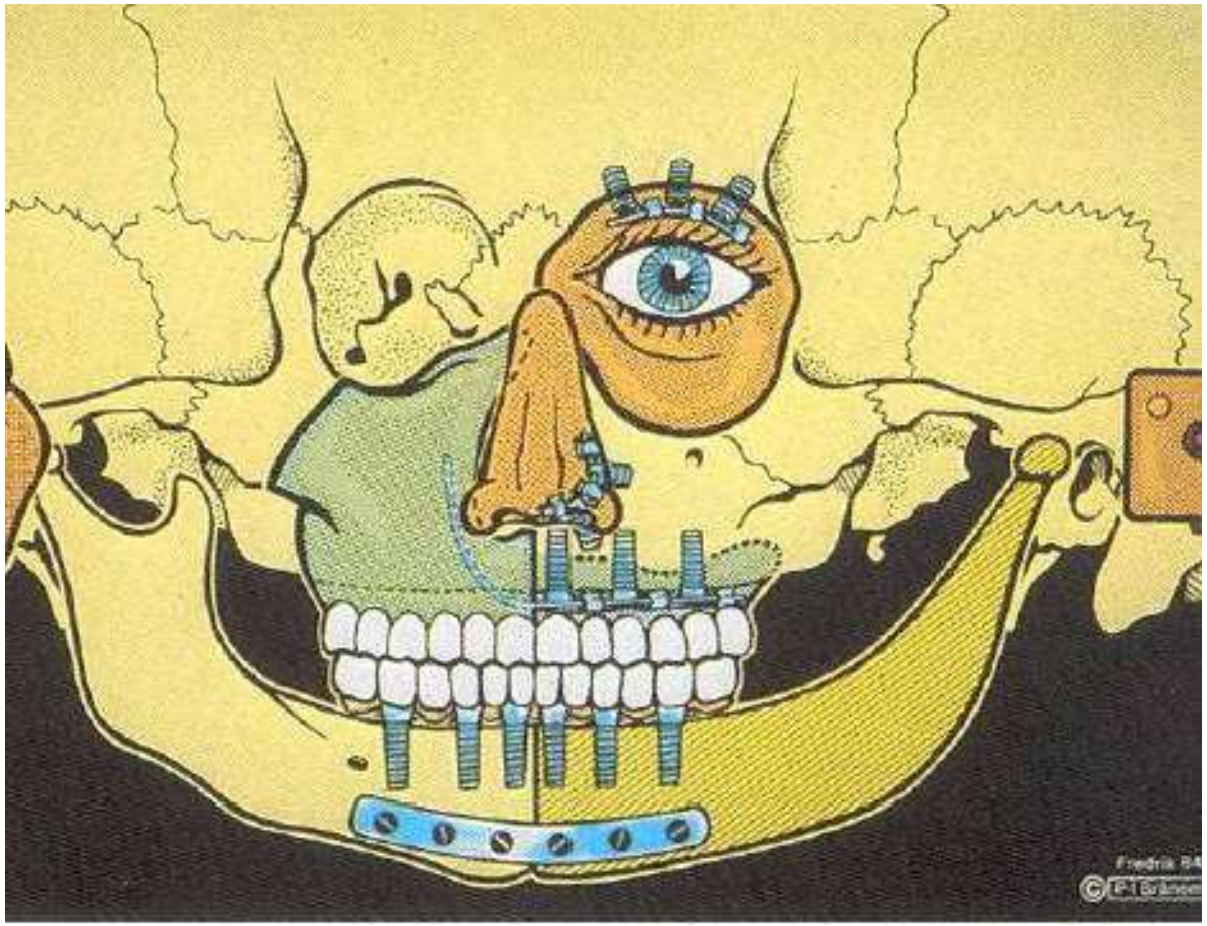
## WHO NEEDS A SOCKET?

# What is Osseointegration?

- Discovered in the1950s that bone can integrate with titanium components
- Nature allows bone cells to attach to the titanium surface and the result is a firm and permanent anchorage for a prosthetic reconstruction



*Color enhanced electro topographic photo of bone cell growing onto titanium*



# Pioneering Work: Professor PI Brånemark

First identified the benefits of osseointegration in dental and maxillofacial restoration as well as bone anchored hearing aids.

# Pioneering Work: Dr. Rickard Brånemark

1998 Dr. Brånemark expanded upon his father's work to amputations

He continues to refine the surgical procedures, instrumentation, implants and rehabilitation protocols have led to the OPRA™ Implant System

This is the only FDA approved system in the US

# Why do we need osseointegration?

Complaints about traditional socket designs:

- Discomfort, sores and pain
- Limited range of motion
- Difficulties donning and doffing prosthesis
- Challenges of volume/weight gain or loss
- Sockets need to be replaced every 2-3 years
- Not applicable for short limbs
- Rejection of prosthesis
- Too many appointments with prosthetist
- Skin irritation and hygiene

**20%** of individuals with non-vascular amputations do not use their prosthesis on a daily basis*

*Hagberg, K. & Brånemark, R. (2001). Consequences of non-vascular trans-femoral amputation: a survey of quality of life, prosthetic use and problems. Prosthetics and Orthotics International, 2001, 25, 186-1

# OPRA™ Osseoanchored Prosthetic Rehabilitation for Amputees

THE ONLY FDA-APPROVED SOLUTION

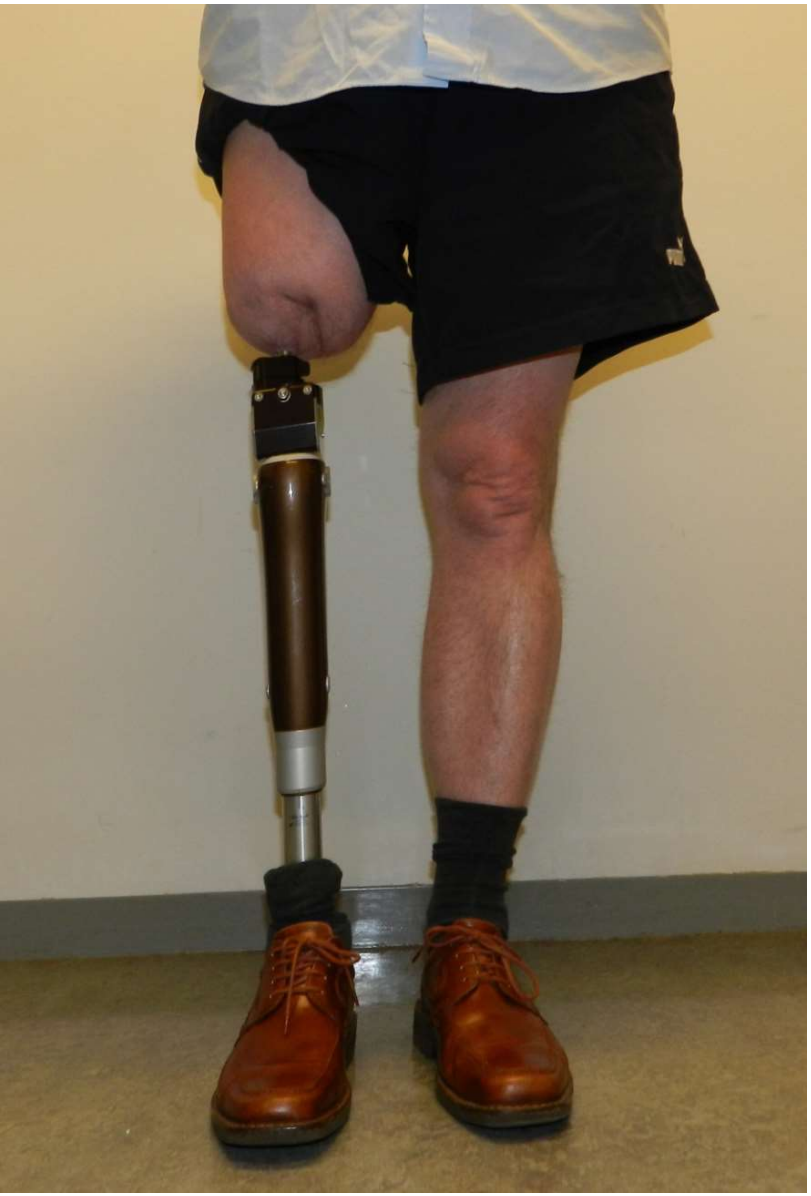
In July of 2015 Integrum became the first and only company to receive FDA approval in the United States for the Osseoanchored Prostheses for the Rehabilitation of Amputees, or OPRA™ Implant System for above knee amputees (ref HDE#H080004).

- Humanitarian Device: Up to 8,000 surgeries per year; not full market approval

The device is indicated for use in patients with transfemoral amputation due to trauma or cancer and who has rehabilitation problems with or cannot use conventional socket prosthesis. The effectiveness of this device for this use has not been demonstrated.

Other types of FDA Approvals:

- Investigational device:  recruit subject for approved study
- Compassionate device: approval for individual cases



# The FDA - Who is Eligible Indications

Documented socket issues with TRANSFEMORAL amputation:

- Recurrent skin issues – ulcers
- Pain
- Short limb length
- Scarring/Skin Grafts
- Excessive Sweating
- Restricted Mobility
- Ages 22-65
- Under 220 pounds

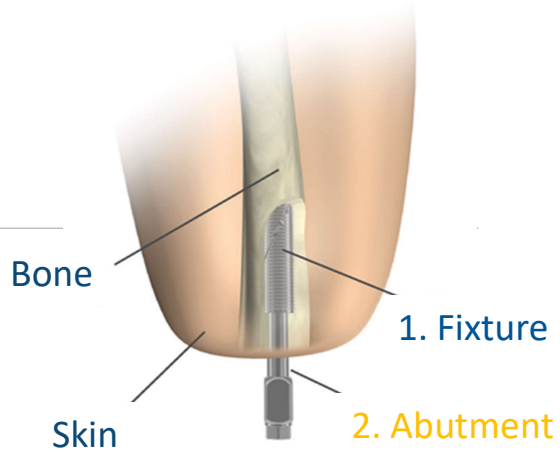
# The FDA - Who is NOT Eligible Contraindications

Transtibial amputation
Upper limb amputations
Patients with severe PVD & poorly controlled Diabetes
Patients who have not finished growing
Patients who exceed 220 pounds
Patients who are pregnant
Osteoporosis/poor bone density
High impact activities
Shorter than 3” femur

# The Solution: Osseoanchored Prostheses

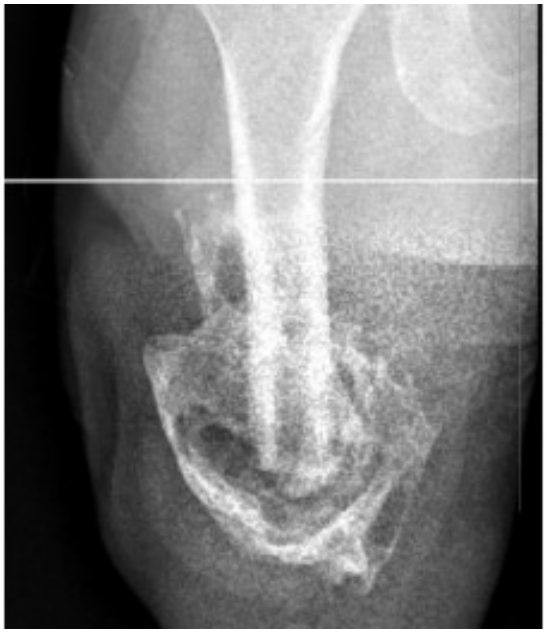
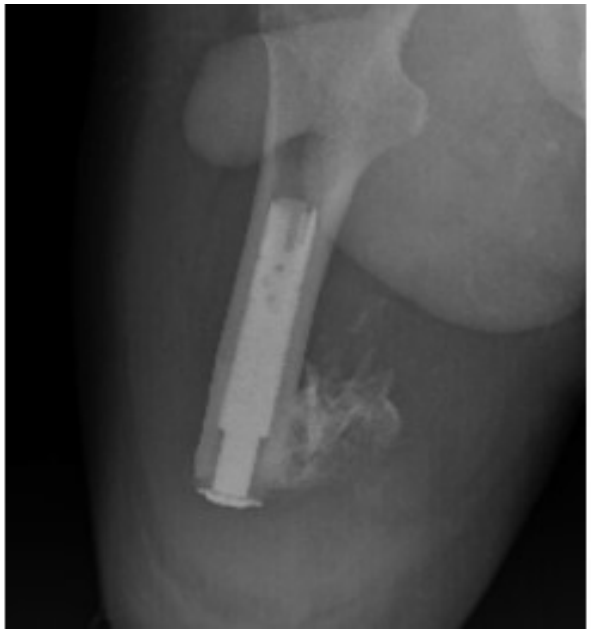
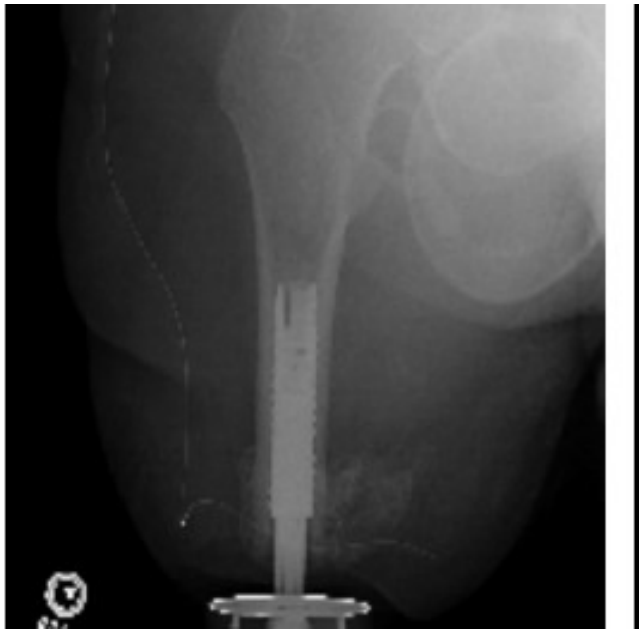
Prosthesis connects directly to the skeleton with no socket and a modular design with three main parts:

1. Fixture: Anchoring element inserted into the patient's bone
2. Abutment: Skin penetrating connection attached to the fixture
3. Axor IITM: Connection device between abutment & prosthesis





The system's 3-part design protects the patient by avoiding bone fractures from accidental loads

# Transfemoral Implant

# The OPRA Treatment Protocol

### 1 PATIENT SCREENING

Each individual that would like to be considered for the OPRA™ Implant System should participate in a patient evaluation and intake process.

### 2 STAGE 1 SURGERY (S1)

The bone of the femur is prepared to receive the fixture (threaded cylinder implant) and it is precisely threaded into the medullary canal of the bone and once in place the soft tissues and skin are closed.

### 3 HEALING PERIOD

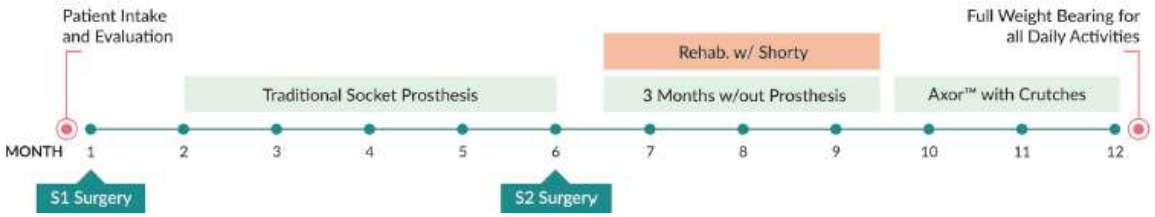
Following the S1 surgery a six month period of healing is achieved to allow the bone tissue to thoroughly integrate around the implant. During this healing period a traditional socket prosthesis can be utilized.

### 4 STAGE 2 SURGERY (S2)

In the S2 surgery the abutment is attached to the fixture and protrudes through the skin. The muscles of the limb are re-attached near the end of the bone and the skin surrounding the area where the abutment exits the skin is prepared in a meticulous surgical procedure. The wound is sutured closed and now the abutment protrudes through the skin.

### 5 REHABILITATION

Approximately three weeks following the completion of the S2 surgery the partial loading of the limb with a "shorty" prosthesis begins. At this point the use of the definitive prosthesis with the Axor™ is initiated and within an additional twelve weeks of progressive loading individuals are free to use their bone anchored prosthesis for all daily activities.



# Osseointegration: Cost Projections

Estimated Cost: $100,000 - $150,000 (non-FDA in Aus $80,000)

Supplies/Maintenance:

- AXOR MSRP: $35,000 with 3-year warranty; can be repaired
- Prosthetic components: $20,000 - $120,000 with 3 – 6-year warranty
- No socket replacements: Savings = $15,000 - $30,000/18-36 months)
- No liners or socks: Savings = $1000 - $2000 annually

Warranty: Unique features of the OPRA system allows for retrofitting as needed with additional surgical costs

Replacement frequency: Surgical replacement? 15 – 30+ years?

Special Considerations:

- Reported impact on components is higher and warranty considerations must be validated
- Limited availability of surgeons trained in procedure

# The Luke Arm

More function for high levels of upper limb loss


# Previous options for Prosthetic Shoulder Joints Ottobock

- Allows free swing up to 40° and abduction up to 20°
- Lock initiated by specific body movement or sound hand eliminating need for harness or switch to engage
- Used with passive or myoelectric devices
- No powered or myoelectric shoulder joint available

# The Mobius Luke Arm

Powered shoulder

Powered humeral rotation, flexion & extension

Up to 10 powered degrees of freedom

Powered wrist flexion/extension

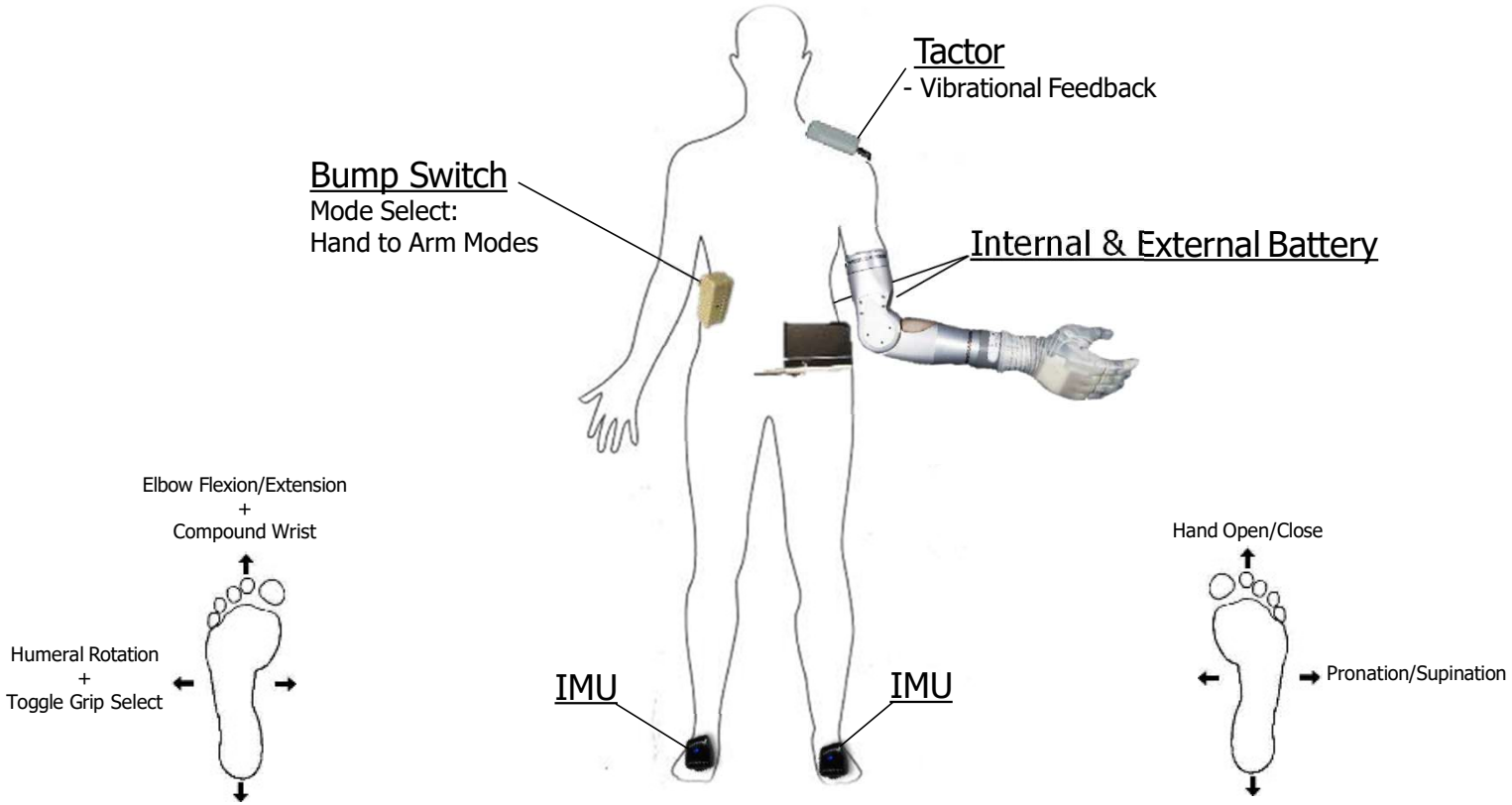
Combined ulnar/radial deviation

Lithium-ion batteries

Wireless foot controls along with all existing inputs

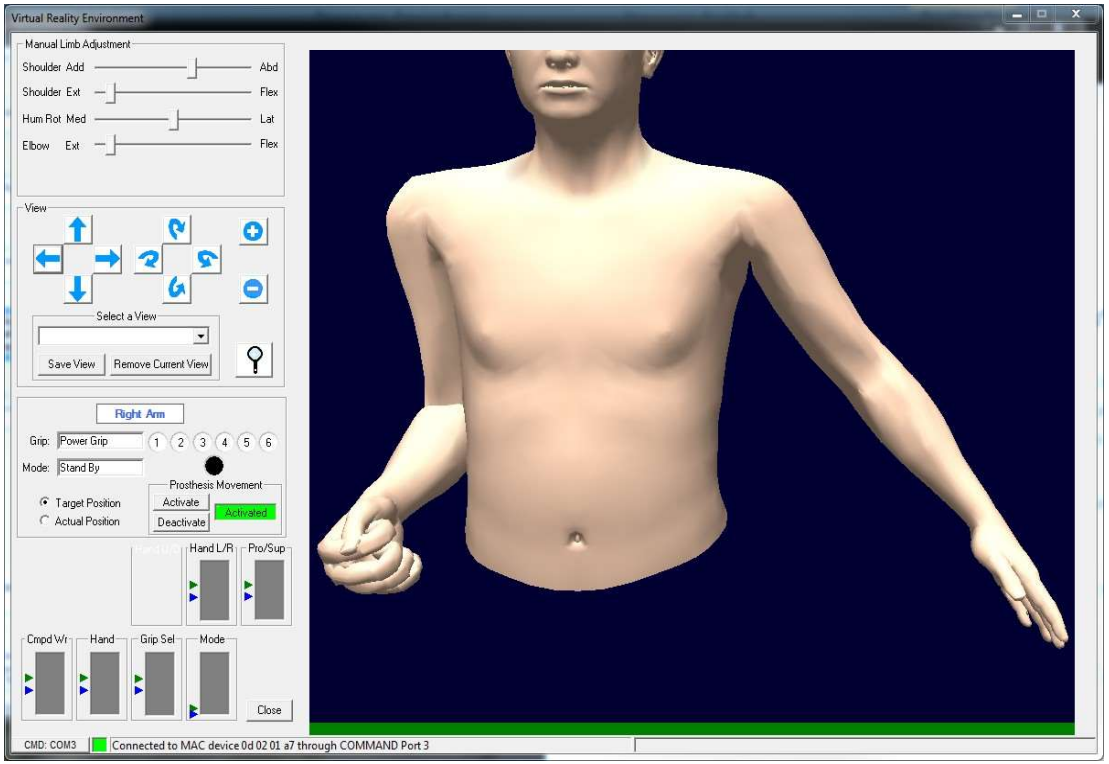
*Photo courtesy of Biodesigns*

# Example Control Scheme



# Training

Virtual reality environment helps clients to practice the arm motions prior to controlling the actual arm.



# Indications

Shoulder disarticulation amputation

Job requirements and/or daily requirements

Bilateral involvement

Proven rejection of alternative myoelectric devices

Commitment and motivation

# Contraindications

- Lack of cognitive ability
- Lack of motivation or commitment
- New prosthetic user
- Concerns about cosmesis
- Weight of device
- Inability to travel to specialized clinics
- Cost

# The Luke Arm: Cost Projections

Estimated Cost: $300,000+ Complete shoulder prosthesis

Supplies/Maintenance: Socket replacement, harnessing, controls, gloves, liners

Warranty: 24 months includes 18-month service. Extended warranty can be purchased.

Replacement frequency: 3 – 5 years

Special Considerations: Regional certified clinics

# CoApt Pattern Recognition

More natural and intuitive control of a myoelectric prosthesis

# Traditional Myoelectric control

Technology introduced in the 1940's

Single or dual site electrodes

Electrode placed on flexors (open) and extensors (close)

Requires co-contraction and fast or slow contractions to control hand

Extensive OT

Often rejected due to:

- Frustration in learning
- Lack of function
- Lack of contact with electrodes leads to inconsistent operation

# Inside of a Socket with CoApt

Captures EMG signal from multiple muscle contractions rather than just two

Uses 9 - 17 dome electrodes

Research began in the 1960's

Commercially available 2013

FDA approved

Hundreds of fittings and becoming the established way to control myoelectric prostheses

# What is it?

COAPT COMPLETE CONTROL

PATTERN RECOGNITION for MYOELECTRIC PROSTHESES

A way of using machine learning and artificial intelligence to ‘decode’ the rich control information in the amputees’ residual limb muscles

A system that learns and adapts to the user, giving them natural control of their prosthesis

It is like voice or facial recognition technologies but specifically designed to recognize muscle signal patterns in order to command a prosthesis

# What are the benefits of CoApt Pattern Recognition?

It enables the user with natural, intuitive prosthesis control.

- ADAPTS TO YOU

It empowers the user with anytime, any place recalibration.

- SEAMLESS TO CONTROL

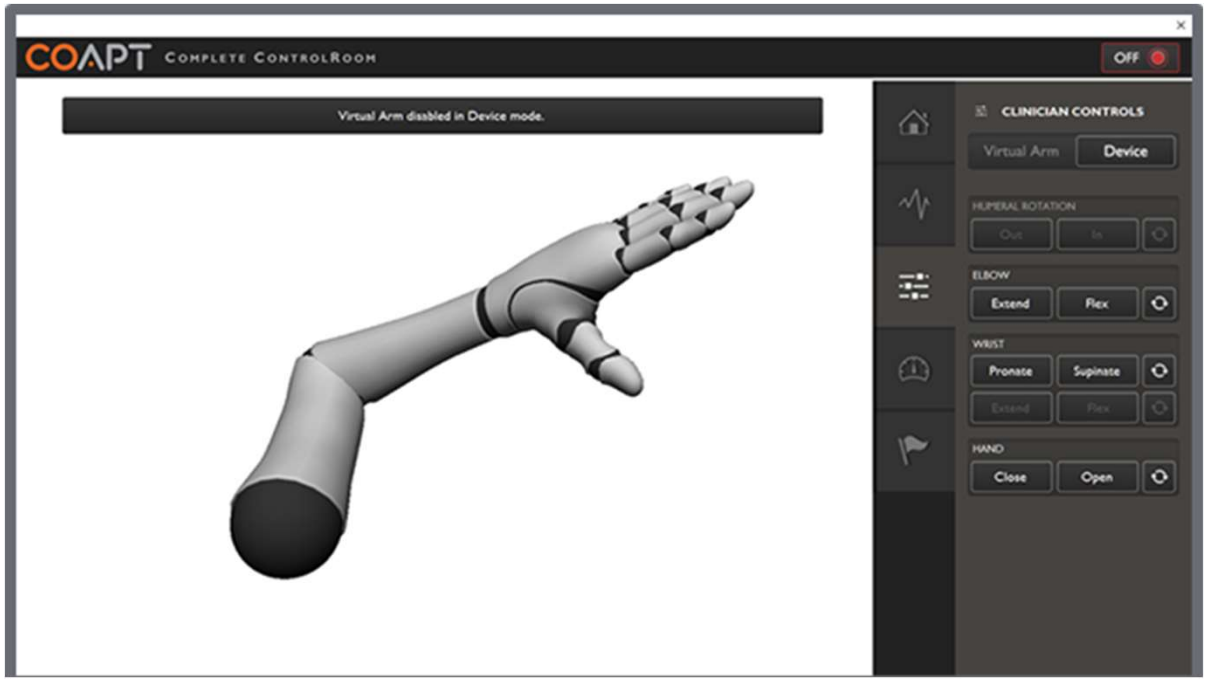
It simplifies fitting and maintenance: less time spent tinkering.

- EASY TO SET UP

It improves prosthesis function with use.

- FULL CONTROL OF SPEED

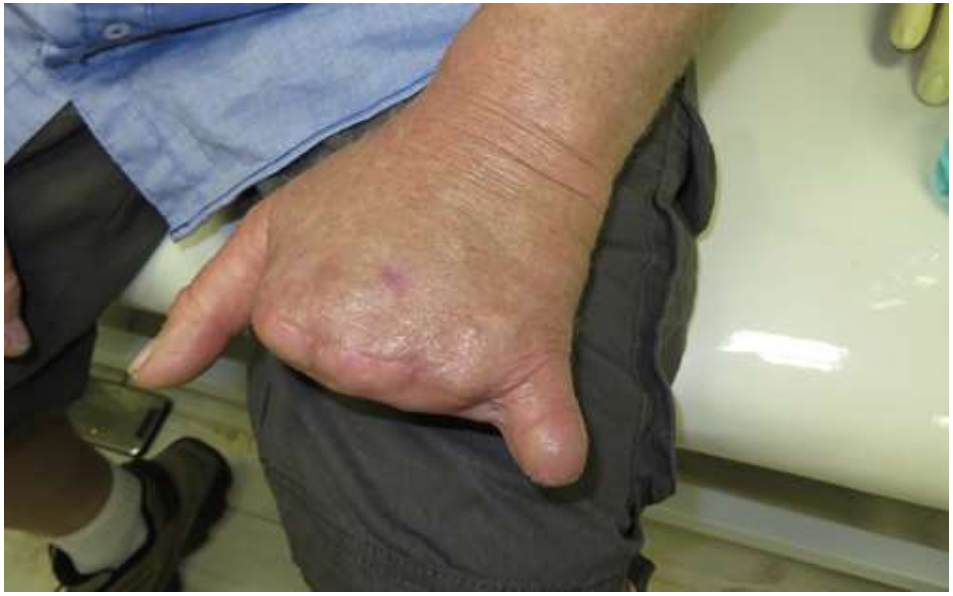
It reduces rate of rejection or abandonment.




# Pattern Recognition Training


# Indications

- Users desiring intuitive prosthesis control
- Transradial or higher-level limb difference or absence
- Users with poor myosite isolation
- Users having weak or unbalanced myosignals
- Users with mode switching challenges
- Fatigue from use of prosthesis
- Volume fluctuation
- Scarred or sensitive limbs
- Poor control throughout range of motion



# Contraindications

Some patients with brachial plexopathy

Some high-level, non-TMR amputees

Cost


# CoApt Pattern Recognition: Cost Projections

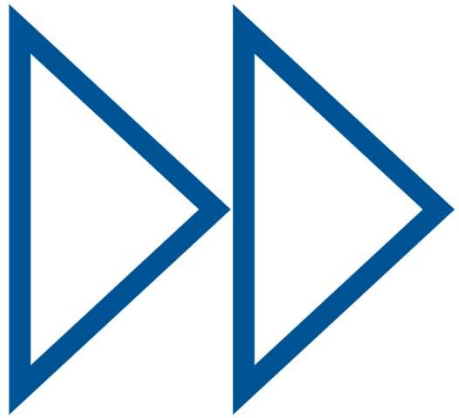
Estimated Cost: MSRP = $44,598 + cost of the socket, hand, elbow, wrist, hook, etc.

Supplies/Maintenance: Included in warranty

Warranty: 1 year with option of warranty extension to 2 or 5 years

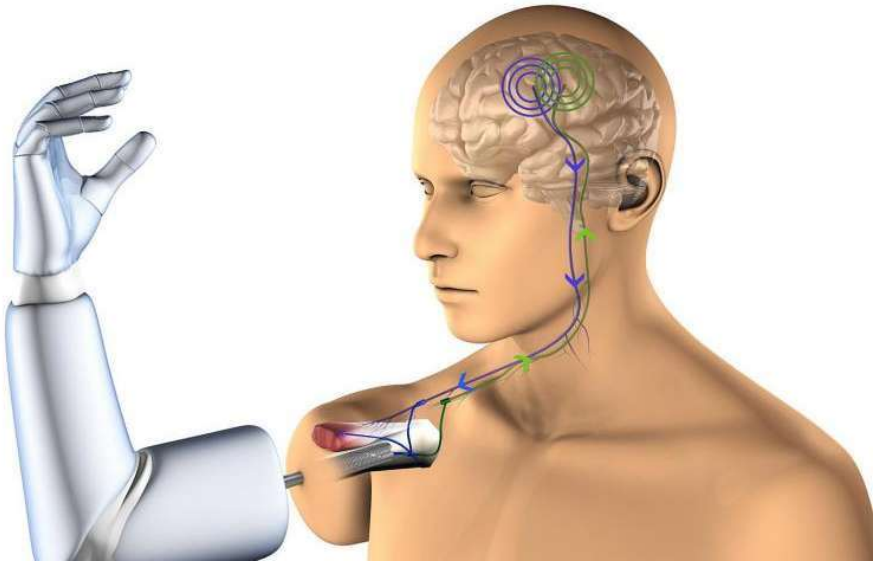
Replacement frequency: 18 – 36 months with socket and device replacements

Special Considerations: Available universally

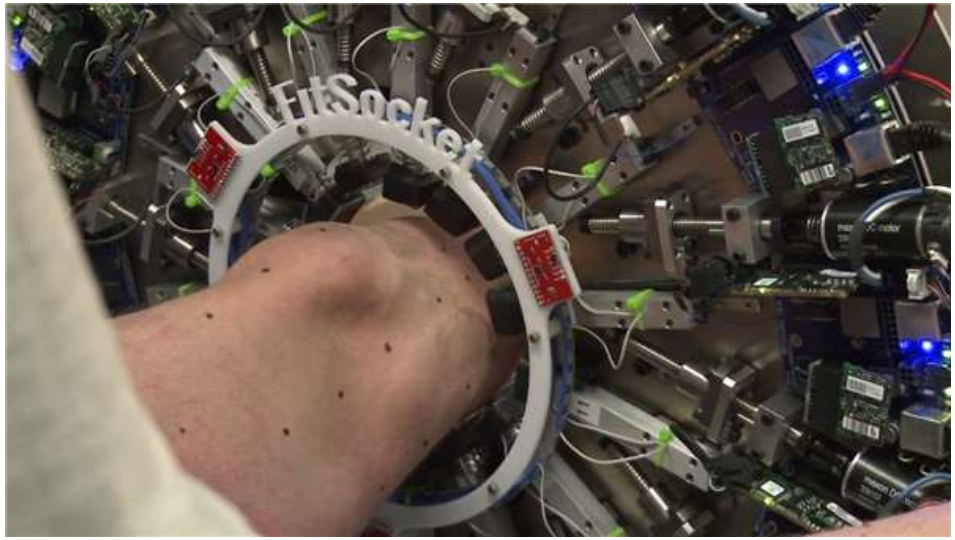


# What’s Next?

# More with Osseointegration



# Nerve Innervation




# Socket Innovation to Accommodate Limb Change

# Sustaining Technology vs. Disruptive Technology

Sustaining technology relies on incremental improvements to an already established technology.

Disruptive technology lacks refinement, often has performance problems because it is new, appeals to a limited audience and may not yet have a proven practical application.

"The Innovator's Dilemma", Clayton M. Christensen 1997

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# Thank you!

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