DoD LUKE ARM Clinical Implementation Plan

Background

The development of the DEKA Arm was funded by the Defense Advanced Research Projects Agency's (DARPA) Revolutionizing Prosthetics program in 2006. By 2008, DARPA had built and tested the first-generation DEKA Arm and developed the second-generation (gen 2) prototype. DARPA used feedback from both the DoD/VA study and from studies of their own subjects to refine the prosthetic prototype and made numerous iterative changes to features and software. Major hardware and design changes were introduced in the third-generation (gen 3) DEKA Arm prototype. The FDA approved the DEKA Arm System on May 9, 2014, paving the way for the device to be manufactured, marketed, and made available in the VA health system.

The DEKA system is a huge leap forward in technology from existing prosthetic arms and hands. The DEKA Arm offers a variety of firsts: It has multiple powered joints and degrees of freedom and can carry out several movements at the same time. It uses an array of sensors and switches and has wireless control. The wrist and fingers adjust into six different grips, enabling users to perform a range of everyday functions: picking up a grape or a glass, holding a tube of toothpaste, turning a key in a lock, using a power tool.

The majority of amputees in this study expressed a desire to receive the DEKA Arm, a device which provides multiple powered degrees of freedom and is operated predominantly by foot controls. The majority reported functional advantages of the DEKA Arm over their existing prostheses.

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Upon commercialization, the DEKA Arm is now called the LUKE arm. It is a modular prosthetic arm that is configurable for different levels of amputation including transradial, transhumeral, and shoulder disarticulation. In its maximum configuration, it has 10 powered degrees of freedom including a powered shoulder, humeral rotator, and wrist flexor with ulnar/radial deviation. Multiple powered degrees of freedom can be moved at the same time. The hand has many preprogrammed grips using four individually controlled degrees of freedom. The hand also includes a sensor that provides grip force feedback. The LUKE arm provides resistance against light rain and fine dust, allowing wearers peace of mind when using the arm outside the home.

The LUKE Arm has a very flexible control system that allows the arm to be controlled by a variety of input devices. Familiar input devices may be used such as surface EMG electrodes and pressure switches. In addition, the LUKE arm may be controlled by intuitive wireless IMUs (inertial measurement

units) that are typically worn on top of the shoes. The clinical team and the client work together to develop the input configuration that best meets the client's needs.

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Product Specifications	Radial	Humeral	Shouider
Weight	1.4 kg	3.4 kg	4.7 kg
Voltage	14.8 V (nominal)		
Battery Type	Li-Ion (rechargeable)		
Battery Capacity	Up to 5000 mAh	Up to 7000 mAh	
Operating Temperature	-10° C to 50° C (14° F to 122° F)		

Powered Joints	Radial	Humeral	Shouider
Multi-articulating Hand	✓	✓	✓
Wrist Flexor with Ulnar/Radial Deviation	✓	✓	✓
Wrist Rotator	✓	✓	✓
Elbow Flexor		✓	✓
Humeral Rotator		✓	✓
Shoulder Flexor			✓
Shoulder Abductor			✓

Evaluation (Pathway for those who have participated in research protocols vs. those who have not)

1. Remote Screening Procedures
    a. Screening Inclusion and Exclusion Criteria
    b. Other screening considerations (willingness to travel, commitment to training, etc.)
    c. Screening Form
    d. Referral Process
    e. Points of Contact / Contact Information

2. In-person Evaluation
    a. Travel considerations
    b. Intake/Evaluation Form(s)
    c. Fitting Trial
        i. Fitting Process
        ii. Training Protocol
        iii. Outcome Assessments
    d. Candidacy Determination: A comprehensive interdisciplinary evaluation and assessment, performed by providers at an MHS Advanced Rehabilitation Center (ARC), is coordinated and documented in the MHS medical record.

Critical components include but are not limited to:
a. Patient demographics
b. Past medical history
c. Functional evaluation including Self-care/Activities of daily living

d. Physical examination including:
    i. Musculoskeletal and neurologic examination including range of motion
    ii. LE and UE strength
    iii. Muscle tone/spasticity
    iv. Residual Limb and intact hand strength and function
f. Anthropometric measures including:
    i. Height
    ii. Weight
g. Skin integrity
h. Cognition
i. Psychosocial assessment
☐ Includes identification of at least one reliable companion that will participate in required comprehensive training and will provide supervision if/when the Veteran uses the device in home and community settings.
j. Environmental assessment
k. Vision
l. Pregnancy for female patients
m. Travel considerations (Includes associated functional, cognitive and psychosocial skills and ability to be away from home for an extended period of time)

The amputation care coordinator will work with the referring facility to coordinate resources and to develop a plan for both travel and lodging, when indicated.

The comprehensive interdisciplinary evaluation and assessment documents the extent to which inclusion criteria are met and exclusion criteria are ruled out.

Inclusion and Exclusion Criteria

INCLUSION CRITERIA
1. Subject is at least 18 years old.
2. Subject has a single or bilateral upper limb amputation.
3. Subject is able to understand the requirements of the study.
4. Subject has active control over one or both ankles, OR has an appropriate number of myoelectric and/or other control sites.

EXCLUSION CRITERIA
1. Subject is an amputee with elbow disarticulation, wrist disarticulation or partial hand amputations.
2. Length of the residual limb would prohibit socket fitting (as determined by the study prosthetist).
3. Subject has significant uncorrectable visual deficits that would impair the ability to see the prosthesis.
4. Subject has major communication deficits.
5. Subject has a skin condition (such as burns, poor skin coverage, or severe contractures) that prevented prior prosthetic wear.
6. Subject uses an electrically controlled medical device including: pacemaker, implanted defibrillator or drug pump.

7. Subject who has neuropathy, uncontrolled diabetes, insensate feet, severe phantom pain, a history of skin ulcers, is receiving dialysis or has any other significant comorbidity which would interfere with the study.
8. Subject has severe circulatory problems including peripheral vascular disease and pitting edema.
9. Subject has cognitive deficits or mental health problems that would limit their ability to participate fully in the study protocol.
10. Subject is pregnant or planning to become pregnant in the near future.
11. Subject works for a prosthetic company that is considered a competitor for the LUKE Arm technology in the future.
12. Subject takes medication which poses a risk for operating heavy equipment.

Training (Once determined to be appropriate candidate)

1. Training Protocol at ARC
2. ARC Discharge Criteria
3. Training Protocol at beneficiary's local MTF, VA or civilian care facility

Monitoring and Outcome Assessment

1. Timing of Follow-up at local facility
2. Timing of Follow-up at ARC
3. Outcome Assessments and Assessment Schedule

Repairs/Replacement/Warranty Considerations:

Walter Reed National Military Medical Center has a memorandum of agreement (MOA) with DARPA for access to ten LUKE Arms to provide to beneficiaries at no cost to the facility. The MOA provides for two years of warranty on the Arm. Once the LUKE Arms are released from DARPA to VA or DoD beneficiaries, an additional 10+ LUKE Arms are available for purchase through Mobius, with a two year warranty. MHS needs to roadmap how to manage warranty issues past the two year point once fitted on a beneficiary.

Attachments:

1. LUKE Arm Clinician Information and Initial Screening Form (MHS)
2. LUKE Arm Patient Information Sheet (MHS)
3. LUKE Arm Training Protocol (MHS)
4. Luke Arm Outcomes Assessment and Program Evaluation (MHS)