

Statement of Work
Microkeratome Systems and Installation
Southeast Louisiana Veterans Health Care System
New Orleans, LA
01/25/2016

1. PURPOSE

- 1.1 The overall purpose is to provide and install Microkeratome System at the Southeast Louisiana Veterans Health Care System (SLVHCS) Diagnostic and Treatment Building Room 3E220 2400 Canal St, New Orleans, LA 70119.

2. SCOPE

- 2.1 The Contractor shall provide, transport, install, and test all listed equipment. All products must meet all salient characteristics defined in this section.
- 2.2 All equipment and installation must meet manufacturers and VA specifications.
- 2.3 The Contractor shall furnish all supplies, equipment, facilities and services required for delivery and installation of the supplies and equipment.
- 2.4 The Contractor is responsible for any missing parts and components not included in order to carry out the installation.

2.5.1 Keratoplasty System

Moria CBm Lamellar Keratoplasty System P007 OR EQUIVALENT

Specifications/Salient characteristics:

- Generator Unit
 - AT-LEAST TWO PERFORMANCE PUMPS
 - Capable of slow vacuum release
 - Built in back up battery
 - Capable of utilizing standard us electrical socket
 - Must include standard us power cord
 - Must at a minimum meet the following compliance standards
 - IEC 60601-1
 - CE 0120
 - 93/42/EEC
 - ISO 9001-2008 version
 - ISO 13485-2003 version
 - FDA compliant
 - Inlet console supply of at-least 4-6 bars and a psi range of at-least 58-87
 - External fuse that allows for at-least 500mA of switching power
 - Must include at-least two manuals
 - Must include a dual stage regulator
- System must include at a minimum the following items or equivalent
 - 1 moist chamber
 - 1 nitrogen gas hose compatible with system
 - 1 blade extractor
 - Bag of at-least 100 head cleaning brushes
 - 1 artificial chamber base for Assisted Lamellar Keratoplasties
 - At-least 1 300 Assisted Lamellar Keratoplasties CBm head
 - At-least 1 350 Assisted Lamellar Keratoplasties CBm head
 - At-least 1 Assisted Lamellar Keratoplasties guide ring with cover
 - At-least 1 turbine
 - At-least 1 turbine hose
 - At-least one carrying case
 - At-least two sterilization boxes

- Must include at-least two manuals

2.5.2 Artificial Chamber Pressure System

MORIA G0 OR EQUIVALENT

SPECIFICATIONS/SALIENT CHARACTERISTICS:

- Artificial Chamber pressure system that must include at the minimum the following items or equivalent
 - 1 artificial chamber pressure system
 - 1 footswitch with standard U.S. Power cord that is compatible with system
 - 1 power supply for artificial chamber pressure system
 - 1 carrying case for system
 - 1 supply cord
 - Artificial chamber pressure system must include at-least 2 user manuals
- Must be capable of pressure monitoring in the preparation ophthalmic tissue

2.5.3 Single Blade Keratoplasty System

MORIA SBK SYSTEM OR EQUIVALENT

SPECIFICATIONS/SALIENT CHARACTERISTICS:

- GENERATOR UNIT
 - At-least two performance pumps
 - Capable of slow vacuum release
 - Built in back up battery
 - Capable of utilizing standard us electrical socket
 - Must include standard us power cord
 - Must at a minimum meet the following compliance standards
 - IEC 60601-1
 - CE 0120
 - 93/42/EEC
 - ISO 9001-2008 VERSION
 - ISO 13485-2003 VERSION
 - FDA COMPLIANT
 - Inlet console supply of at-least 4-6 bars and a psi range of at-least 58-87
 - External fuse that allows for at-least 500ma of switching power
 - Must include at-least two manuals
 - Must include a dual stage regulator
 - Footswitch
 - Shipping case
- Pre-assembled
- Oscillation rate of at-least 1500 rpm
- Capable of utilizing a disposable blade
- Automated microkeratome
- Must allow for intraoperative visibility
- Hinge that moves towards the patients nose
- Adjustable advance rate
- Flap thickness capabilities of at least the following
 - 100-110 μ m
 - 130-140 μ m
 - 110-120 μ m
 - 100-110 μ m
 - 100-110 μ m

2.5.4 Inflation Syringe and Tubing Set

19183 OR EQUIVALENT

Specifications/Salient Characteristics:

- Must include syringe as well as tubing
- Boxes of at-least 10

2.5.5 Rotational System Head

Moria 19178-110 OR EQUIVALENT

Specifications/Salient Characteristics:

- Cable of being utilized for single pass as well as double pass surgical techniques
- Cable of making conventional and ultra-thin lamellar grafts
- Rotational system head 110 micrometers
- Must be compatible with Lamellar Keratoplasty System
- Disposable

2.5.6 Rotational System Head

Moria 19178-130 OR EQUIVALENT

Specifications/Salient Characteristics:

- Cable of being utilized for single pass as well as double pass surgical techniques
- Cable of making conventional and ultra-thin lamellar grafts
- Rotational system head 130 micrometers
- Must be compatible with Lamellar Keratoplasty System
- Disposable

2.5.7 Rotational System Head

Moria 19178-200 OR EQUIVALENT

Specifications/Salient Characteristics:

- Cable of being utilized for single pass as well as double pass surgical techniques
- Cable of making conventional and ultra-thin lamellar grafts
- Rotational system head 200 micrometers
- Must be compatible with Lamellar Keratoplasty System
- Disposable

2.5.8 Rotational System Head

Moria 19178-250 OR EQUIVALENT

Specifications/Salient Characteristics:

- Cable of being utilized for single pass as well as double pass surgical techniques
- Cable of making conventional and ultra-thin lamellar grafts
- Rotational system head 250 micrometers
- Must be compatible with Lamellar Keratoplasty System
- Disposable

2.5.9 Rotational System Head

Moria 19178-300 OR EQUIVALENT

Specifications/Salient Characteristics:

- Cable of being utilized for single pass as well as double pass surgical techniques
- Cable of making conventional and ultra-thin lamellar grafts
- Rotational system head 300 micrometers
- Must be compatible with Lamellar Keratoplasty System
- Disposable

2.5.10 Rotational System Head

Moria 19178-350 OR EQUIVALENT

Specifications/Salient Characteristics:

- Cable of being utilized for single pass as well as double pass surgical techniques
- Cable of make conventional and ultra-thin lamellar grafts
- Rotational system head 350 micrometers
- Must be compatible with Lamellar Keratoplasty System
- Disposable

2.5.11 Rotational System Head

Moria 19178-50 OR EQUIVALENT

Specifications/Salient Characteristics:

- Cable of being utilized for single pass as well as double pass surgical techniques
- Cable of make conventional and ultra-thin lamellar grafts
- Rotational system head 50 micrometers
- Must be compatible with Lamellar Keratoplasty System
- Disposable

2.5.12 Rotational System Head

Moria 19178-90 OR EQUIVALENT

Specifications/Salient Characteristics:

- Cable of being utilized for single pass as well as double pass surgical techniques
- Cable of make conventional and ultra-thin lamellar grafts
- Rotational system head 90 micrometers
- Must be compatible with Lamellar Keratoplasty System
- Disposable

2.5.13 Surface Ablation System

Moria SETKL OR EQUIVALENT

Specifications/Salient Characteristics:

- Must be capable of being utilized in refractive surgery
- Must allow for the customization of the patients eye utilizing the status of the patients cornea
- System must not require the utilization of alcohol to perform procedures
- Must allow for surgeon to have the option to reposition patients epithelial flap
- Automatic system with an adjustable advance rate that utilizes an applanation plate
- Must utilize a blunt edge cutting mechanism that is disposable and comes pre-assembled
- System must allow for the customization of flap diameters
- System must include at least one reusable suction ring and at-least one large reusable suction ring
- Must include handpiece storage box designed to hold the surface ablation system
- Must include at-least two sterilization box designed for utilization with the suction rings
- Must include at-least 1 bag of at a minimum 100 cleaning brushes
- Must include surface ablation system manual as well as guidelines for the utilization of
- System must utilize at-least two electrical motors
- Capable of being utilize on flat corneas, and for wavefront ablations as well as larger ablations that require the utilization of a laser
- System must be able to be operated with a single hand
- Capable of performing both automated and linear epikeratome procedures

2.5.14 Artificial Chamber Pressure Chamber System Tubing

Moria 19192 OR EQUIVALENT

Specifications/Salient Characteristics:

- Must come in boxes of at-least 10
- Must be compatible with artificial chamber pressure system

2.5.15 Cleaning Brushes

Moria 19149 OR EQUIVALENT

Specifications/Salient Characteristics:

- Must be capable of cleaning hand pieces and single blade keratoplasty system
- Must come in bags of at-least 10

2.5.16 Single Blade Keratoplasty System Rotational Head

Moria 19184-110 OR EQUIVALENT

Specifications/Salient Characteristics:

- Cable of being utilized for single pass as well as double pass surgical techniques
- Cable of making conventional and ultra-thin lamellar grafts
- Rotational system head 110 micrometers
- Must be compatible with Single Blade Keratoplasty System
- Disposable

2.5.17 Single Blade Keratoplasty System Rotational Head

Moria 19184-130 OR EQUIVALENT

Specifications/Salient Characteristics:

- Cable of being utilized for single pass as well as double pass surgical techniques
- Cable of making conventional and ultra-thin lamellar grafts
- Rotational system head 130 micrometers
- Must be compatible with Single Blade Keratoplasty System
- Disposable

2.5.18 Single Blade Keratoplasty System Rotational Head

Moria 19184-200 OR EQUIVALENT

Specifications/Salient Characteristics:

- Cable of being utilized for single pass as well as double pass surgical techniques
- Cable of making conventional and ultra-thin lamellar grafts
- Rotational system head 200 micrometers
- Must be compatible with Single Blade Keratoplasty System
- Disposable

2.5.19 Single Blade Keratoplasty System Rotational Head

Moria 19184-250 OR EQUIVALENT

Specifications/Salient Characteristics:

- Cable of being utilized for single pass as well as double pass surgical techniques
- Cable of making conventional and ultra-thin lamellar grafts
- Rotational system head 250 micrometers
- Must be compatible with Single Blade Keratoplasty System
- Disposable

2.5.20 Single Blade Keratoplasty System Rotational Head

Moria 19184-300 OR EQUIVALENT

Specifications/Salient Characteristics:

- Cable of being utilized for single pass as well as double pass surgical techniques
- Cable of making conventional and ultra-thin lamellar grafts
- Rotational system head 300 micrometers
- Must be compatible with Single Blade Keratoplasty System
- Disposable

2.5.21 Single Blade Keratoplasty System Rotational Head

Moria 19184-350 OR EQUIVALENT

Specifications/Salient Characteristics:

- Cable of being utilized for single pass as well as double pass surgical techniques
- Cable of make conventional and ultra-thin lamellar grafts
- Rotational system head 350 micrometers
- Must be compatible with Single Blade Keratoplasty System
- Disposable

2.5.22 Single Blade Keratoplasty System Rotational Head

Moria 19184-400 OR EQUIVALENT

Specifications/Salient Characteristics:

- Cable of being utilized for single pass as well as double pass surgical techniques
- Cable of make conventional and ultra-thin lamellar grafts
- Rotational system head 400 micrometers
- Must be compatible with Single Blade Keratoplasty System
- Disposable

2.5.23 Single Blade Keratoplasty System Rotational Head

Moria 19184-450 OR EQUIVALENT

Specifications/Salient Characteristics:

- Cable of being utilized for single pass as well as double pass surgical techniques
- Cable of make conventional and ultra-thin lamellar grafts
- Rotational system head 450 micrometers
- Must be compatible with Single Blade Keratoplasty System
- Disposable

2.5.24 Single Blade Keratoplasty Ring

Moria 19336/90 OR EQUIVALENT

Specifications/Salient Characteristics:

- Size -1
- Ring shaped
- Compatible with Single blade Keratoplasty system
- Boxes of at-least 10
- Disposable

2.5.25 Single Blade Keratoplasty Ring

Moria 19337/90 OR EQUIVALENT

Specifications/Salient Characteristics:

- Size 0
- Ring shaped
- Compatible with Single blade Keratoplasty system
- Boxes of at-least 10
- Disposable

2.5.26 Single Blade Keratoplasty Head with Ring

Moria 19336/130 OR EQUIVALENT

Specifications/Salient Characteristics:

- Size 0

- Ring shaped
- 130 micrometer head
- Compatible with Single blade Keratoplasty system
- Boxes of at-least 10
- Disposable

2.5.27 Single Blade Keratoplasty Head with Ring
Moria 19337/130 OR EQUIVALENT

Specifications/Salient Characteristics:

- Size -1
- Ring shaped
- 130 micrometer head
- Compatible with Single blade Keratoplasty system
- Boxes of at-least 10
- Disposable

2.5.28 Large Single Blade Keratoplasty Head
Moria 19354/130 OR EQUIVALENT

Specifications/Salient Characteristics:

- Large Cut
- 130 micrometer head
- Compatible with Single blade Keratoplasty system
- Boxes of at-least 10
- Disposable

2.5.29 Large Single Blade Keratoplasty Head
Moria 19354/110 OR EQUIVALENT

Specifications/Salient Characteristics:

- Large Cut
- 130 micrometer head
- Compatible with Single blade Keratoplasty system
- Boxes of at-least 10
- Disposable

3. WARRANTY

8.1 The contractor shall provide a one year manufacturer's warranty on all parts and labor.

8.2 The warranty shall include all travel and shipping costs associated with any warranty repair.