

**Stryker RemB System
NXREP-17-151-7702
Salient Characteristics
9/12/2017**

SEPG Number:	
EER Number:	
IFCAP Tracking Number:	
PO Number:	
Contracting Number:	
FORCE Planning Number:	
Temporary Transaction Number:	

1. Contracting Officer's Technical Representative (COTR).

Name:	
Section:	Research and Development
Address:	Rm 516, Building 1, VA Puget Sound Healthcare, 1660 S Columbian Way, Seattle, WA 98108
Phone Number:	
E-Mail Address:	

2. Contract Title

Stryker RemB System

3. Background

The RR&D Center for Limb Loss and Mobility conducts numerous studies involving cadaveric tissue in support of (a) foot and ankle cadaveric gait simulation for orthopaedic procedures, (b) mechanical and histological analysis of tissue to evaluate the effect of injury and disease on tissue function, and (c) to validate portions of the biplane fluoroscopy system used to track foot bone motion. Such studies require some degree of specimen preparation such as dissection and tissue harvest.

Currently, we have a bone saw system that is past end-of-life and failing. This system is no longer safe for users to work with due to intermittent loss of power and heating issues and has thus been retired. This is a significant disruption to our research; in order to continue our research, we had to rent the Stryker RemB CORE system for two months at \$3000/month.

We seek to replace our failing Stryker system and cease renting the RemB system by purchasing the Styker RemB system including a number of accessories for expanded flexibility and ease when dissecting and preparing specimens.

This upgrade is being obtained through ORD funds, and will be immediately usable in 1D-133 of building 100 of the VA Puget Sound-663.

4. Salient Characteristics

The surgical bone saw system must satisfy the following requirements:

- Foot and hand control for a single accessory
- Support wire drivers, drill and saw accessories
- Come with wire drivers or wire driver attachments, drill attachments, and saw accessories
- Saw must be compatible with ~1cm wide blades or smaller
- Saw must be able to cut at least ~30mm deep or more
- Operate two simultaneous hand pieces
- Operate using standard 120VAC, 60Hz single-phase power
- Below is a list of the Stryker RemB items for procurement and their use:

Product #	Description	Unit	Quantity	Use
5400050000	CORE Powered Instrument Driver	Each	1	Power supply necessary for use of any accessory
6400034000	RemB Electric Sagittal Saw	Each	1	Small bone saw for small and precise cuts
6400099000	RemB Electric Universal Driver	Each	1	For insertion of kirshner wire and small Steinmann pins (threaded or non-) into bone or for creating pilot holes in bone
4100110000	AO Small Drill	Each	1	For smoothing small areas of bone
4100125000	Pin Collet (2.0-3.2mm)	Each	1	Addition to Universal Driver for pin insertion or pilot hole creation
4100131000	1/4" Drill with Key	Each	1	For smoothing/removing medium size areas of bone
5100008000	TPS Footswitch IPx7	Each	1	For operation of accessories by foot
5100004000	TPS Cord	Each	2	For operation of accessories
	5 years of Procure	Years	5	For immediate swapping of accessories if damaged & bi-annual proactive inspections

5. Other Pertinent Information or Special Considerations

- The equipment will be set up in Building 100, Room 1D-133B of the VA Puget Sound-663 until the completion of the B101 Mental Health and Research Building (expected by end of calendar year 2017). The equipment will then be moved to room GW03B in that building.
- This equipment will be purchased using ORD funds.

Delivery Information

a.) Delivery Address:

VAPSHCS
 Center for Limb Loss and Mobility
 Building 100, Room 1D-133B
 1660 S. Columbian Way, MS151
 Seattle, WA 98108

b.) Delivery Contacts:





Privacy Officer Language for Statement of Work (SOW)

- Information made available to the contractor or subcontractor by VA for the performance or administration of this contract or information developed by the contractor/subcontractor in performance or administration of the contract shall be used only for those purposes and shall not be used in any other way without the prior written agreement of the VA. This clause expressly limits the contractor/subcontractor's rights to use data as described in Rights in Data- General, FAR 52.227-14(d) (1).

- VA information should not be co-mingled, if possible, with any other data on the contractors/subcontractor's information systems or media storage systems in order to ensure VA requirements related to data protection and media sanitization can be met. If co-mingling must be allowed to meet the requirements of the business need, the contractor must ensure that VA's information is returned to the VA or destroyed in accordance with VA's sanitization requirements. VA reserves the right to conduct on-site inspections of contractor and subcontractor IT resources to ensure data security controls, separation of data and job duties, and destruction/media sanitization procedures are in compliance with VA directive requirements.

- Prior to termination or completion of this contract, contractor/subcontractor must not destroy information received from VA, or gathered/created by the contractor in the course of performing this contract without prior written approval by the VA. Any data destruction done on behalf of VA by a contractor/subcontractor must be done in accordance with National Archives and Records Administration (NARA) requirements as outlined in VA Directive 6300, Records and Information Management and its Handbook 6300.1 Records Management Procedures, applicable VA Records Control Schedules, and VA Handbook 6500.1, Electronic Media Sanitization. Self-certification by the contractor that the data destruction requirements above have been met must be sent to the VA Contracting Officer within 30 days of termination of the contract.

- The contractor/subcontractor must receive, gather, store, back up, maintain, use, disclose and dispose of VA information only in compliance with the terms of the contract and applicable Federal and VA information confidentiality and security laws, regulations and policies. If Federal or VA information confidentiality and security laws, regulations and policies become applicable to the VA information or information systems after execution of the contract, or if NIST issues or updates applicable FIPS or Special Publications (SP) after execution of this contract, the parties agree to negotiate in good faith to implement the information confidentiality and security laws, regulations and policies in this contract.

- The contractor/subcontractor shall not make copies of VA information except as authorized and necessary to perform the terms of the agreement or to preserve electronic information stored on contractor/subcontractor electronic storage media for restoration in case any electronic equipment or data used by the contractor/subcontractor needs to be restored to an operating state. If copies are made for restoration purposes, after the restoration is complete, the copies must be appropriately destroyed.

Records Management Language for Contracts Required

The following standard items relate to records generated in executing the contract and should be included in a typical Electronic Information Systems (EIS) procurement contract:

1. Citations to pertinent laws, codes and regulations such as 44 U.S.C chapters 21, 29, 31 and 33; Freedom of Information Act (5 U.S.C. 552); Privacy Act (5 U.S.C. 552a); 36 CFR Part 1222 and Part 1228.
2. Contractor shall treat all deliverables under the contract as the property of the U.S. Government for which the Government Agency shall have unlimited rights to use, dispose of, or disclose such data contained therein as it determines to be in the public interest.
3. Contractor shall not create or maintain any records that are not specifically tied to or authorized by the contract using Government IT equipment and/or Government records.
4. Contractor shall not retain, use, sell, or disseminate copies of any deliverable that contains information covered by the Privacy Act of 1974 or that which is generally protected by the Freedom of Information Act.
5. Contractor shall not create or maintain any records containing any Government Agency records that are not specifically tied to or authorized by the contract.
6. The Government Agency owns the rights to all data/records produced as part of this contract.
7. The Government Agency owns the rights to all electronic information (electronic data, electronic information systems, electronic databases, etc.) and all supporting documentation created as part of this contract. Contractor must deliver sufficient technical documentation with all data deliverables to permit the agency to use the data.
8. Contractor agrees to comply with Federal and Agency records management policies, including those policies associated with the safeguarding of records covered by the Privacy Act of 1974. These policies include the preservation of all records created or received regardless of format [paper, electronic, etc.] or mode of transmission [e-mail, fax, etc.] or state of completion [draft, final, etc.].
9. No disposition of documents will be allowed without the prior written consent of the Contracting Officer. The Agency and its contractors are responsible for preventing the alienation or unauthorized destruction of records, including all forms of mutilation. Willful and unlawful destruction, damage or alienation of Federal records is subject to the fines and penalties imposed by 18 U.S.C. 2701. Records may not be removed from the legal custody of the Agency or destroyed without regard to the provisions of the agency records schedules.
10. Contractor is required to obtain the Contracting Officer's approval prior to engaging in any contractual relationship (sub-contractor) in support of this contract requiring the disclosure of information, documentary material and/or records generated under, or relating to, this contract. The Contractor (and any sub-contractor) is required to abide by Government and Agency guidance for protecting sensitive and proprietary information.