

STATEMENT OF WORK:
AUGUST 30, 2017

1.0 INTRODUCTION:

1. Background. The Department of Veterans Affairs (VA) has identified the Cook Stent and Balloon or equal as candidate items for consolidated contracting through the Prosthetics Clinical Management Program. The purpose of consolidated contracting is to obtain user uniformity and quality products at lower than current contract and open-market prices.
2. Salient Characteristics.

Brand name or equal to:

A. Cook Medical - Zilver self-expanding stents:

- FDA vascular approval on vascular sizes (6-10mm diameters)
- FDA biliary approval on biliary sizes (4, 5, 12, 14mm diameters)
- Delivery catheter length: 80 and 125cm
- Low Profile (all sizes shall go through a 6F sheath)
- Pin and Pill delivery system
- Radiopaque band on delivery system
- 4 gold markers on proximal and distal end of stent for visibility
- 92.9% patency at 9 months
- Optimal balance of flexibility, strength and durability to prevent fracture and potential restenosis

B. Cook Medical - Zilver PTX Drug-Eluting Stent:

- drug-eluting peripheral stent for above-the-knee femoropopliteal arteries
- FDA vascular approval on vascular sizes (4-9mm diameters)
- Total lesion lengths up to 140mm per limb and 280mm per patient
- 125 cm over-the-wire delivery system
- Minimum sheath Fr: 6mm
- Wire guide diameter: .035in
- Delivery catheter diameter: 6, 7, and 8
- Delivery catheter length: 40, 60, 80, 100, and 120cm
- stent releases paclitaxel within 72 hours of implantation
- 83.4% patency at 2 years

C. Cook Medical - Advance® 14LP Low-Profile PTA Balloon:

- Lowest profile in .014 balloons to cross highly stenosed lesions (all sizes shall go through a 4F sheath)
- Peripheral shaft design for flexibility, support and kink-resistance when working below knee
- Fast inflation and deflation times for quicker restoration of blood flow
- Hydrophilic balloon to help with crossing tight lesions
- Wide variety of sizes: balloon diameter: 2, 2.5, 3 and 4mm diameters; balloon length: 20-200mm lengths
- Delivery length: 170cm to go all the way down to the foot if necessary
- Monorail system so don't need exchange length wire

D. Cook Medical - Advance® 35LP Low-Profile PTA Balloon:

- Lowest profile in .035 balloons (almost all sizes shall go through a 5F sheath) to cross highly stenosed lesions
- D-shaped lumen for rapid inflation and deflation for faster restoration of blood flow
- Starcast shoulders on balloon for rewinding balloon for repeated use of product in same procedure
- Wide variety of sizes: balloon sizes: 3-12mm in diameter; 20-140mm in length
- Delivery length: 80 and 135cm options
- Over-the-wire system

3. Purpose and Objectives. The purpose of this solicitation is to establish supply sources that will provide the contracted items for Prosthetics and Sensory Aids Services at the Department of Veterans Affairs Palo Alto Health Care System (VAPAHCS). The objectives are to insure availability and consistency of product for ease of usage and to obtain volume-based, committed use pricing.
4. Agreement Duration. The consignment agreement will be a five (5) year blanket purchase agreement.
5. Agreement Effective Date. The effective date of the agreement shall be **10 days (or sooner upon mutual agreement) after the date of award.**
6. Award by CLIN Item. Award will be made by CLIN item. All relevant items must be included in the offer/s. As detailed in the solicitation each offeror is required to offer their complete product line. The intended scope of this agreement includes all current and future product line items. The solicitation details the pricing information required to be submitted for these line items. Prices will be established for each of the product line items. VA recognizes that this market is not static and we need to have access to state-of-the-art technology. Therefore, in addition to the items initially agreed upon, the scope of this agreement includes all items which become available during the course of the agreement which are in the product line. New or modified items within the awarded product line may be added to or deleted from the agreement at a later date in accordance with paragraph 5.0 Technology Refresh.
7. Multiple Award. This solicitation will result in a *minimum of one (1) firm fixed-priced* consignment agreements.

2.0 EXTENT OF OBLIGATION:

1. The Contractor shall furnish all supplies listed in Part I, Supplies/Services and Prices/Costs on a consignment basis to the VAPAHCS in accordance with the terms and conditions of this consignment agreement. Items as listed shall be placed at the VA Medical Center, stocked in a secured area agreed upon by the Contractor and Contracting Officer's Representative(s) (COR's) and as described by the product labeling, at no expense to the Government. The Contractor shall provide all items in strict conformance to the VA Physician's prescription that has been provided by the prescribing VA Facility. The solicitation only includes commercial items. Products that are not commercial items are considered experimental and purchase of experimental products shall not be authorized under this solicitation.

The associated North American Industrial Classification System (NAICS) code for this procurement is 339113, with a small business size standard of 750 employees.

2. Estimated Quantities. There is no expressed or implied guarantee that the estimated quantities below will be purchased under this agreement. Actual quantities may exceed or be less than those represented below. See Schedule of Supplies for par level by line item.

The below are annual estimated quantities:

- | | |
|-------------|----------|
| A. Stents | 80 each |
| B. Balloons | 300 each |

3. Exclusions. Agreements resulting from this solicitation will not preclude VA from purchasing items from non-contract sources.
4. Consignment Agreement – An agreement for a specified period of time during which the Contractor provides an item to the Government, reimbursement for which is made only if and when the Government makes use of the item. Unused items are returned to the Contractor at the end of the effective period of the agreement without reimbursement or other expense to the Government. For the purposes of this agreement, use of item(s) or used item(s) shall be defined as “implanted, opened, or lost”.

The Government assumes no liability for any item(s) assigned to the VAPAHCS on a consignment basis until a requirement for the item exists and a purchase or delivery order is placed against the agreement. Title for the consigned items shall remain with the agreement or until the items are used.

Payment for items furnished under the agreement is applicable only when such items are used (implanted), the package is opened, or "lost" by the VA. Contractor agrees to accept the Government Purchase Card as the preferred method of payment.

The contractor shall assign a representative to the facility to initiate and oversee the consignment inventory.

5. Network Contracting Office (NCO) 21 contracting officers, purchasing agents, and ordering officers are authorized to issue orders under this agreement.
6. The Certification and Accreditation requirements do not apply, and that a Security Accreditation Package is not required.
7. Contracting Officer's Representative (COR) - Individual or Individuals designated by the Contracting Officer to place orders, furnish technical guidance, advice, certify invoices, and provide general supervision of the work performed under the executed agreement. This definition is not to be construed as authorization to interpret or furnish advice and information to the Contractor relative to the financial or legal aspects of the agreement. Enforcement of these segments is vested in and is the responsibility of the Contracting Officer. The COR and/or the Contracting Officer will be the only medical centers personnel authorized to request services under this agreement.
8. The Contractor shall deliver FOB destination, the supplies on an as needed basis when requested by the Contracting Officer or his/her designee. Only the Contracting Officer or designee will be authorized to coordinate and request consignment items direct from the Contractor.
9. **Contractor Selection by Medical Center. Ordering Procedures:** As a multiple award, blanket purchase agreement (BPA) vehicle, calls are governed by FAR 13.303-5(c) & (d), which provides that each awardee must be given a fair opportunity to be considered for each order exceeding \$3500, unless a statutory exception applies.

After award, individual orders for these highly specialized items will be based on the unique circumstances of each procedure, taking into account individual patient needs and physician training.

10. **Quarterly Reports:** Contractor shall furnish the Contracting Officer a Quarterly Usage/Saving Report.

3.0 DELIVERY:

1. **DELIVERY REQUIREMENTS.** The Contractor shall deliver FOB destination, the supplies on an as needed basis when requested by the Contracting Officer or his/her designee. Only the Contracting Officer or designee will be authorized to coordinate and request consignment items direct from the contractor.
2. **JUST-IN-TIME DELIVERY.** Normal delivery time is within 48 hours after receipt of order Monday through Friday. Urgent delivery is upon receiving notification no later than 2:00 PM local time the day before delivery, the awardees shall supply to appropriate facility personnel all required items by 10:30 AM the following day. Orders must be received and delivered five (5) days per week in these situations. Orders may be made orally, faxed, e-mailed, written or by delivery order.
3. **ADDITIONAL ACCESSORY ITEMS.** If needed, the Contractor shall provide to the VA staff if applicable any additional accessory items (i.e., sizers, handles and trays) that are handled, but not implanted for the consigned products in this Agreement.

Based on case scheduling, Contractor may be required to have additional accessory set(s) for the implant procedures at no additional cost to the Government.

4.0 CONSIGNMENT AGREEMENT:

1. **INITIAL INVENTORY:** The products listed on the “Initial Inventory Schedule” represent the products that must be available for the initial inventory. The initial inventory required for each product is shown in the Initial Inventory Schedule below. However, this level may be changed by written notification of the Contracting Officer. The Contractor shall place the products at the designated location(s) within the time specified, or if no time specified, no later than ten (10) calendar days after receipt of the fully executed contract. Each facility will provide adequate space/shelving for stocking these products. The contractor shall provide a complete listing of model and part numbers to the Contracting Officer’s Representative (COR) upon delivery of the initial inventory.
2. **INVENTORY LEVEL:** All consignment inventories will be coordinated with the COR. The contractor agrees to coordinate with the COR to maintain the inventory level of product at all times. At no time shall the number of products held on consignment fall below the minimum quantity specified without the concurrence of the CO, and a contract modification. If it is discovered that the stock quantities fall below the agreed minimum stock level, the contractor must replenish the stock level with like quantities of items within 48 hours at no additional expense to the Government.

INVENTORY SCHEDULE

MFR#	Catalog #	Product Description	Par Level
G38482	ZISV6-35-125-6-120-PTX	Zilver PTX 35 Drug-Eluting Stent	6
G38463	ZISV6-35-125-6-40-PTX	Zilver PTX 35 Drug-Eluting Stent	2
G38479	ZIV6-35-125-6-60-PTX	Zilver PTX 35 Drug-Eluting Stent	2
G38480	ZISV6-35-125-6-80-PTX	Zilver PTX 35 Drug-Eluting Stent	2
G38481	ZISV6-35-125-6-100-PTX	Zilver PTX 35 Drug-Eluting Stent	2
G38486	ZISV6-35-125-7-40-PTX	Zilver PTX 35 Drug-Eluting Stent	2
G38487	ZISV6-35-125-7-60-PTX	Zilver PTX 35 Drug-Eluting Stent	2
G38488	ZISV6-35-125-7-80-PTX	Zilver PTX 35 Drug-Eluting Stent	2
G38489	ZISV6-35-125-7-100-PTX	Zilver PTX 35 Drug-Eluting Stent	2
G39490	ZISV6-35-125-7-120-PTX	Zilver PTX 35 Drug-Eluting Stent	3
G38495	ZISV6-35-125-8-40-PTX	Zilver PTX 35 Drug-Eluting Stent	1
G38516	ZISV6-35-125-8-60-PTX	Zilver PTX 35 Drug-Eluting Stent	1
G38518	ZISV6-35-125-8-80-PTX	Zilver PTX 35 Drug-Eluting Stent	1
G38523	ZISV6-35-125-8-100-PTX	Zilver 635 Vascular Self-Expanding Stent	0
G43856	ZIV6-35-80-8-40	Zilver 635 Vascular Self-Expanding Stent	2
G43855	ZIV6-35-80-8-30	Zilver 635 Vascular Self-Expanding Stent	2
G43857	ZIV6-35-80-8-60	Zilver 635 Vascular Self-Expanding Stent	2
G43861	ZIV6-35-80-9-40	Zilver 635 Vascular Self-Expanding Stent	2
G43864	ZIV6-35-80-10-20	Zilver 635 Vascular Self-Expanding Stent	2
G43866	ZIV6-35-80-10-40	Zilver 635 Vascular Self-Expanding Stent	2
G43819	ZIV6-35-125-6-20	Zilver 635 Vascular Self-Expanding Stent	2
G43820	ZIV6-35-125-6-30	Zilver 635 Vascular Self-Expanding Stent	2
G50313	PTAX4-14-170-2-2	Advance® 14LP Low-Profile PTA Balloon	2
G50314	PTAX4-14-170-2-4	Advance® 14LP Low-Profile PTA Balloon	1
G50315	PTAX4-14-170-2-6	Advance® 14LP Low-Profile PTA Balloon	1
G50316	PTAX4-14-170-2-8	Advance® 14LP Low-Profile PTA Balloon	1
G50317	PTAX4-14-170-2-12	Advance® 14LP Low-Profile PTA Balloon	1
G50318	PTAX4-14-170-2-16	Advance® 14LP Low-Profile PTA Balloon	1
G50319	PTAX4-14-170-2-20	Advance® 14LP Low-Profile PTA Balloon	2
G50320	PTAX4-14-170-2.5-2	Advance® 14LP Low-Profile PTA Balloon	1

G50321	PTAX4-14-170-2.5-4	Advance® 14LP Low-Profile PTA Balloon	1
G50322	PTAX4-14-170-2.5-6	Advance® 14LP Low-Profile PTA Balloon	1
G50323	PTAX4-14-170-2.5-8	Advance® 14LP Low-Profile PTA Balloon	1
G50324	PTAX4-14-170-2.5-12	Advance® 14LP Low-Profile PTA Balloon	2
G50325	PTAX4-14-170-2.5-16	Advance® 14LP Low-Profile PTA Balloon	2
G50326	PTAX4-14-170-2.5-20	Advance® 14LP Low-Profile PTA Balloon	2
G50327	PTAX4-14-170-3-2	Advance® 14LP Low-Profile PTA Balloon	1
G50328	PTAX4-14-170-3-4	Advance® 14LP Low-Profile PTA Balloon	1
G50329	PTAX4-14-170-3-6	Advance® 14LP Low-Profile PTA Balloon	1
G50330	PTAX4-14-170-3-8	Advance® 14LP Low-Profile PTA Balloon	1
G50331	PTAX4-14-170-3-12	Advance® 14LP Low-Profile PTA Balloon	2
G50332	PTAX4-14-170-3-16	Advance® 14LP Low-Profile PTA Balloon	2
G50333	PTAX4-14-170-3-20	Advance® 14LP Low-Profile PTA Balloon	2
G52245	PTA5-35-135-3-2.0	Advance® 35LP Low-Profile PTA Balloon	1
G52246	PTA5-35-135-3-4.0	Advance® 35LP Low-Profile PTA Balloon	1
G34375	PTA5-35-135-3-6.0	Advance® 35LP Low-Profile PTA Balloon	1
G52247	PTA5-35-135-3-8.0	Advance® 35LP Low-Profile PTA Balloon	1
G52248	PTA5-35-135-3-10.0	Advance® 35LP Low-Profile PTA Balloon	1
G52249	PTA5-35-135-3-12.0	Advance® 35LP Low-Profile PTA Balloon	2
G52250	PTA5-35-135-3-14.0	Advance® 35LP Low-Profile PTA Balloon	2
G34376	PTA5-35-135-3-17.0	Advance® 35LP Low-Profile PTA Balloon	2
G34377	PTA5-35-135-3-20.0	Advance® 35LP Low-Profile PTA Balloon	2
G52251	PTA5-35-135-4-2.0	Advance® 35LP Low-Profile PTA Balloon	1
G52252	PTA5-35-135-4-4.0	Advance® 35LP Low-Profile PTA Balloon	1
G35528	PTA5-35-135-4-6.0	Advance® 35LP Low-Profile PTA Balloon	1
G52253	PTA5-35-135-4-8.0	Advance® 35LP Low-Profile PTA Balloon	1
G52254	PTA5-35-135-4-10.0	Advance® 35LP Low-Profile PTA Balloon	1
G52255	PTA5-35-135-4-12.0	Advance® 35LP Low-Profile PTA Balloon	1
G52256	PTA5-35-135-4-14.0	Advance® 35LP Low-Profile PTA Balloon	1
G34380	PTA5-35-135-4-17.0	Advance® 35LP Low-Profile PTA Balloon	2
G35527	PTA5-35-135-4-20.0	Advance® 35LP Low-Profile PTA Balloon	2
G52257	PTA5-35-135-5-2.0	Advance® 35LP Low-Profile PTA Balloon	1
G52258	PTA5-35-135-5-4.0	Advance® 35LP Low-Profile PTA Balloon	1
G52259	PTA5-35-135-5-6.0	Advance® 35LP Low-Profile PTA Balloon	1
G52260	PTA5-35-135-5-8.0	Advance® 35LP Low-Profile PTA Balloon	1
G52261	PTA5-35-135-5-10.0	Advance® 35LP Low-Profile PTA Balloon	2
G52262	PTA5-35-135-5-12.0	Advance® 35LP Low-Profile PTA Balloon	2
G52263	PTA5-35-135-5-14.0	Advance® 35LP Low-Profile PTA Balloon	2
G35531	PTA5-35-135-5-17.0	Advance® 35LP Low-Profile PTA Balloon	2
G35532	PTA5-35-135-5-20.0	Advance® 35LP Low-Profile PTA Balloon	3
G52264	PTA5-35-135-6-2.0	Advance® 35LP Low-Profile PTA Balloon	1
G52265	PTA5-35-135-6-4.0	Advance® 35LP Low-Profile PTA Balloon	1
G52266	PTA5-35-135-6-6.0	Advance® 35LP Low-Profile PTA Balloon	1
G52267	PTA5-35-135-6-8.0	Advance® 35LP Low-Profile PTA Balloon	2
G52268	PTA5-35-135-6-10.0	Advance® 35LP Low-Profile PTA Balloon	2
G52269	PTA5-35-135-6-12.0	Advance® 35LP Low-Profile PTA Balloon	2
G52270	PTA5-35-135-6-14.0	Advance® 35LP Low-Profile PTA Balloon	2
G35535	PTA5-35-135-6-17.0	Advance® 35LP Low-Profile PTA Balloon	2
G35536	PTA5-35-135-6-20.0	Advance® 35LP Low-Profile PTA Balloon	3
G52271	PTA5-35-135-7-2.0	Advance® 35LP Low-Profile PTA Balloon	1
G52272	PTA5-35-135-7-4.0	Advance® 35LP Low-Profile PTA Balloon	1
G52273	PTA5-35-135-7-6.0	Advance® 35LP Low-Profile PTA Balloon	1
G52274	PTA5-35-135-7-8.0	Advance® 35LP Low-Profile PTA Balloon	1
G52275	PTA5-35-135-7-10.0	Advance® 35LP Low-Profile PTA Balloon	2

G52276	PTA5-35-135-7-12.0	Advance® 35LP Low-Profile PTA Balloon	2
G52277	PTA5-35-135-7-14.0	Advance® 35LP Low-Profile PTA Balloon	2
G35539	PTA5-35-135-7-17.0	Advance® 35LP Low-Profile PTA Balloon	2
G35540	PTA5-35-135-7-20.0	Advance® 35LP Low-Profile PTA Balloon	2
G52278	PTA5-35-135-8-2.0	Advance® 35LP Low-Profile PTA Balloon	2
G52279	PTA5-35-135-8-4.0	Advance® 35LP Low-Profile PTA Balloon	2
G52280	PTA5-35-135-8-6.0	Advance® 35LP Low-Profile PTA Balloon	2
G52281	PTA5-35-135-8-8.0	Advance® 35LP Low-Profile PTA Balloon	2
G52282	PTA5-35-135-8-10.0	Advance® 35LP Low-Profile PTA Balloon	2
G35545	PTA5-35-135-9-2.0	Advance® 35LP Low-Profile PTA Balloon	2
G52285	PTA5-35-135-9-3.0	Advance® 35LP Low-Profile PTA Balloon	2
G52286	PTA5-35-135-9-4.0	Advance® 35LP Low-Profile PTA Balloon	2
G52287	PTA5-35-135-9-6.0	Advance® 35LP Low-Profile PTA Balloon	2
G52288	PTA5-35-135-9-8.0	Advance® 35LP Low-Profile PTA Balloon	2
G35546	PTA5-35-135-10-2.0	Advance® 35LP Low-Profile PTA Balloon	2
G52292	PTA5-35-135-10-3.0	Advance® 35LP Low-Profile PTA Balloon	2
G52293	PTA5-35-135-10-4.0	Advance® 35LP Low-Profile PTA Balloon	2
G52294	PTA5-35-135-10-6.0	Advance® 35LP Low-Profile PTA Balloon	2
G52295	PTA5-35-135-10-8.0	Advance® 35LP Low-Profile PTA Balloon	2

3. **INVENTORY MANAGEMENT:** The designated contractor's representatives assigned to the facility will periodically (no less than bi-annually) conduct a physical inventory of the consignment inventory and notify the COR if any discrepancy and any outdated items. At a minimum, the report will contain stock utilization and levels and recalled/outdated items found and removed. The excess unused items will be returned to the contractor at the end of the term of the agreement without reimbursement or other expense to the Government, provided that such items are in unopened and undamaged condition.
4. **REPLACEMENT PRODUCTS:** The facility will withdraw products from the consignment stock on a first-in first-out basis. After each procedure, approximately seven-ten (7-10) business days after such procedure the Contracting Officer/purchasing agent will issue an order with an associated purchase order (PO) listing the products used and the vendor shall replace these products within the time specified. If no time is specified, delivery shall be within five (5) days. Replacement products will be shipped/delivered FOB Destination directly to the requesting location at no additional cost to the Government. The PO will serve as authorization for delivery of replacement items and payment for the item(s) used.
5. **PRODUCT STERILIZATION:** If applicable, the contractor shall replace any accessory items such as handles, trays and sizers that are handled, but not implanted. The handled items shall be shipped periodically upon written request by the COR at no additional cost to the Government. Contractor does not re-sterilize products.
6. **ALTERATION OF QUANTITIES:** The contractor agrees that the total quantity of items furnished under the agreement can be changed at any time during the effective period of the agreement. The contractor agrees that from time to time, the contracting officer may change the number of items on consignment by written request. Any such changes shall be mutually agreed upon by the contractor and the Contracting Officer providing a change modification request.
7. **DEFECTIVE PRODUCTS:** The contractor shall replace defective products according to the delivery schedule of the agreement at no additional cost to the Government, unless the facility has misused or lost the product.
8. **EXPIRING INVENTORY:** Inventory having less than 30 days sterility/expiration date must be removed and replaced. The contractor shall provide a list of all the expired products to the COR. The VAPAHCS is not liable for devices that are allowed to expire. These services will be completed at no additional cost to the Government.

9. **EXPIRATION/TERMINATION OF AGREEMENT:** Upon expiration/termination of the agreement, the VAPAHCS will reconcile all consignment stock units. The contractor will remove all unused items at the end of the effective period of the agreement without reimbursement or other expense to the Government, provided that such items are in unopened and undamaged condition.
10. **DELIVERY SCHEDULE:** The vendor shall contact the COR (or COR designee) at the VA to coordinate the delivery of the products. Delivery of the products shall be during normal working hours, between 10:30 AM and 4:00PM Monday through Friday.
11. **UNIT PRICING:** The unit price for each item/implant shall remain the same, as identified in Part I, Supplies/Services and Prices/Costs, throughout the term of this Agreement.
12. **INITIAL INVENTORY LEVELS:** An initial consignment inventory is indicated in the schedule; however, this level may be changed by written mutual written notification of the Contractor and the Contracting Officer. Initial consignment inventory shall be placed in the participating Medical Center(s) within ten (10) calendar days after receipt of Notice of Award.
13. **CONSIGNMENT ITEM OWNERSHIP/TITLE:** The Contractor shall maintain ownership of all consigned items furnished under this Agreement, until such time that the Government uses (implants) the consigned item.
14. **GOVERNMENT SAFEGUARDING OF ITEMS ON GOVERNMENT PREMISES:** The Government is responsible for storing the consignment items and for using the items as indicated by product labeling. Once used, the Government orders a replacement and is invoiced at the agreed price for the used product. The Government will provide proper storage and security for all items supplied hereunder and is responsible for all expenses incidental to the safekeeping and security of items on Government premises.
15. **CONTRACTOR LIABILITY:** The Government shall be held responsible for any consignment item that has been without question damaged, misused, or lost by Government. If the Contractor damages the item, or the item is defective, it shall be replaced by the Contractor, with no re-stocking fees of any kind assessed upon the VA Medical Center. The determination as to whether or not the Government was negligent shall be decided by mutual agreement between the Contractor and the Contracting Officer, based on evidence presented. Disagreements thereafter shall be settled in accordance with the Disputes Clause.
16. **GOVERNMENT LIABILITY:** The Government assumes no liability for any items assigned to the participating medical center on a consignment basis until such time as a requirement for the item exists, a consignment item is used, and a purchase (delivery) order is placed against this consignment agreement. If an item has been opened by the Government and/or damaged or cannot be re-sterilized, the item will be purchased by the medical center. The Government will not be liable for damage due to acts of God, e.g. earthquakes.
17. **CONSIGNMENT EXPIRATION/TERMINATION:** All unused, unopened and undamaged items will be returned to the Contractor at the end of the term of this agreement, or cancellation of this agreement, without reimbursement or any additional expense to medical center. Contractor shall be responsible for all shipping costs associated with their return.
18. **MODIFICATIONS:** Changes to the agreement will be made with mutual consent of both parties. Changes will be made in writing and signed by the Contractor and the Contracting Officer. Neither CORs nor VAPAHCS staff have the authority to make changes to the agreement. The only Government official authorized to make changes to the Agreement is the Contracting Officer.
19. **CONSIGNMENT ITEMS ROTATION:** Contractor shall remove and/or replace items from consignment inventory as necessary. Such items may have 30 days or less remaining before the sterility expiration date. The Contractor shall advise the COR prior to any inventory item(s) being removed or replaced; upon removal or replacement of that item, the COR will sign receipt for that item. The Contractor shall perform these services at no cost to the Government.

20. **PAYMENT/REPLACEMENT:** As consignment items listed under Supplies/Services and Prices/Costs are used, a purchase order will be placed by the Contracting Officer/Purchasing Agent with the Contractor within 48-72 hours of its use, at the price listed in Supplies/Services and Prices/Costs. This purchase order will authorize payment for the used item(s) and will also authorize delivery of the replacement item(s). The purchase order shall be referenced on the invoice and delivery ticket for the replaced items. All replacement items shall be delivered within five (5) business days from receipt of purchase order. Replacement of consignment items is through the Contractor's Customer Service department by providing a purchase/delivery order number including model, size and serial number used, for the consignment items and quantities needed. Contractor will be paid only after consigned item(s) is/are used (implanted) by the Government, at the replacement cost indicated in this agreement. Purchase orders and/or Government credit card may be issued/used for reordering and payment.
21. **PAYMENT PROCEDURES:** Contractor must accept the Government Purchase Card as a form of payment in accordance with procedures outlined in the Continuation of SF 1449 section.
22. **INVENTORY SIGN IN/OUT PROCESS:** The VAPAHCS will develop an inventory accountability process, whereby each and every consigned item shall be accounted for. Contractor shall log each item that they place or remove from the consignment inventory; the item's disposition shall be logged, dated and double signed (Contractor's signature and the COR's signature or COR's designee). COR will log the item's disposition each time an item is removed from inventory. This log sheet shall consist of (at a minimum) the following information:
- a. Date
 - b. Item Description
 - c. Item serial number (or identification number)
 - d. Description of item disposition (Narrative stating what happened to the item)
 - e. Printed Name and Title of person who placed or removed the item
 - f. Signature of item "e" above
 - g. Counter signature (including Printed Name and Title) if required
23. **CONTRACTOR INVENTORY CHECKS:** Contractor shall periodically (at least twice per year) conduct a physical inventory (audit) of the consignment items. Inventory results shall be furnished to the COR.
24. **SPECIAL IMPLANT NEEDS:** Occasionally specific patients may require a special implant not available from the consignment inventory. These items will be purchased from any contractor whose pricing is deemed to be fair and reasonable following all Government rules and regulation as they pertain to the acquisition of supplies. Special use items that become routinely used may be added to this agreement by a modification issued by the Contracting Officer.
25. **DEFECTIVE CONSIGNMENT ITEMS/GUARANTEE:** Contractor shall replace defective consignment items or related supplies at no charge to the Government. The consignment items shall be subject to the terms and conditions specified in the warranty information for each individual item. All items will be in proper working condition as required by applicable quality standards.

5.0 TECHNOLOGY REFRESH:

1. All implants, instruments, and accessories offered shall be state-of-the-art technology. "State-of-the-art" is defined as the most recently designed components which are announced for marketing purposes, available, maintained and supported in accordance with requirements specified in the solicitation. Components and products with a manufacturer's planned obsolescence within the first year of award are not acceptable.
2. If upgrades of implants or supplies become available after award of this agreement, the contractor and Government shall mutually agree to adding replacement items for the awarded items.
3. The contractor will provide to the contracting officer the following information:

- (1) A list of specific awarded items which shall be updated.
 - (2) Product literature for the new items and a detailed description of the differences between the awarded items and the new items, and a specific analysis of the comparative advantages/ disadvantages of the items involved.
4. The Contracting Officer will provide the information to the Program Office for approval. Upon approval, the agreement will be modified to acknowledge the updated items.
5. Upon mutual agreement, new products may replace awarded items during the term of this Agreement. If pricing for new products is unacceptable, medical centers will continue to use current products on agreement and contractor will be required to continue to supply the agreement items.

6.0 ON-SITE PERSONNEL REQUIREMENT:

If applicable, Contractor shall endeavor to have qualified personnel available within 120 minutes (2 hours) of reasonable request by the medical center. The technical representative will provide technical information of the contractor's products. At the time of the award, VA will provide the vendor with a list of contact information for that implant device and a list of medical centers that provide clinic follow-up care. Technical support will be available twenty four (24) hours a day on technical issues. Contractor must return telephone calls for assistance within a reasonable time of the medical center's telephone call to the contractor. Upon request, the vendor must provide names of the representatives covering the medical center. If the vendor fails to provide the above information or the needed support the agreement will be terminated.

Upon award, contractor shall inform CORs of appropriate contacts and provide phone numbers.

7.0 PRODUCT MODIFICATION, REMOVAL OR RECALL:

If any product awarded under this solicitation requires modification, is removed or recalled by the contractor or manufacturer due to defects in the product or potential dangers to patients, or if any required modification, removal or recall is suggested or mandated by a regulatory or official agency, the following steps will immediately be taken by the contractor or manufacturer:

- a. Notify Chief, Medical/Surgical Services, VA Palo Alto Medical Center, 3801 Miranda Ave., Palo Alto, CA 94304, in writing, by the most expeditious manner possible. Provide two copies of the notification, which shall include, but not be limited to the following:

- (1) Complete item description and/or identification, order numbers from customers and the agreement number assigned as a result of an award on this solicitation.
 - (2) Reasons for modifications, removal or recall.
 - (3) Necessary instructions for return for credit, replacement or corrective action.

- b. A copy of the notification in a. above shall be provided to:

Assistant Chief Prosthetics
VA Palo Alto Medical Center
3801 Miranda Ave.
Palo Alto, CA 94304

- c. The Contracting Officer shall be provided a copy of the notification in a. above.

8.0 SPD SUPPORT (if applicable):

- i. All items delivered to the medical center shall be accompanied by a complete inventory listing to include lot numbers and expiration dates.
- ii. Vendor or designee shall visit SPD before delivering product to Surgical Suite, so that SPD can verify the inventory list and ensure that the condition of the packaging is intact and are labeled as being sterilized.
- iii. No items shall be marked miscellaneous.

9.0 TRAINING:

If applicable, the Contractor shall provide on-site, in-service training to VA staff as needed.

12.0 AGREEMENT ADMINISTRATION DATA:

The Contracting Officer is the only person authorized to approve changes or modify any of the requirements under this agreement. The Contractor shall communicate with the Contracting Officer on all matters pertaining to agreement administration. Only the Contracting Officer is authorized to make commitments or issue changes which will affect price, quantity, or quality of performance of this agreement. In the event the contractor effects any such change at the direction of any person other than the Contracting Officer, the change shall be considered to have been made without authority and no adjustment will be made in the agreement price to cover any increase in costs incurred as a result thereof.

13.0 ID BADGES/PARKING/SMOKING POLICY:

- a. **CONTRACTOR SIGN-IN** – Contractor personnel shall report to Acquisition and Material Management Service, before visiting the facilities, to sign-in and receive a contractor's security badge.
- b. **BADGES** – All Contractor personnel are required to wear identification (ID) badges during the entire period during which they are on VA grounds. ID badges must show an identification picture, name of the individual, and the represented company.
- c. **PARKING** – It is the responsibility of Contractor personnel to park only in designated parking areas. Parking information is available from the VA Security Service. The VA will not invalidate or make reimbursement for parking violations of the Contractor's personnel under any circumstances.
- d. **SMOKING** – Smoking is not permitted within or around the VA Healthcare System facilities, except in designated areas.

(END STATEMENT OF WORK)