

JUSTIFICATION FOR SINGLE SOURCE AWARDS IAW [FAR 13.106-1](#)
(OVER MICRO-PURCHASE THRESHOLD(\$3K) BUT NOT EXCEEDING THE SAT (\$150K))

IAW [FAR13.104](#), COs must promote competition to the maximum extent practicable to obtain supplies and services from the source whose offer is the most advantageous to the Government, considering the administrative cost of the purchase. When competition is not practicable, IAW [FAR13.106-1\(b\)](#), COs solicit from a single source for purchases not exceeding the simplified acquisition threshold. COs may solicit from one source if the CO determines that the circumstances of the contract action deem only one source reasonably available (e.g., urgency, exclusive licensing agreements, brand-name or industrial mobilization). IAW [FAR13.106-3\(b\)\(3\)](#), COs are required to include additional statements ***explaining the absence of competition*** (see [13.106-1](#) for brand name purchases) if only one source is solicited and the acquisition does not exceed the simplified acquisition threshold (does not apply to an acquisition of utility services available from only one source) or supporting the award decision if other than price-related factors were considered in selecting the supplier. This template when completed can be used to document single source awards IAW [FAR13.106-3\(b\)\(3\)](#). Note: Statements such as "only known source" or "only source which can meet the required delivery date" are inadequate to support a sole source purchase.

1. ACQUISITION PLAN ACTION ID:

646-18-3-142-0469

**1A. PROJECT/TASK
No.**

1B. ESTIMATED AMOUNT:

\$113,980.00

2. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES REQUIRED AND THE INTENDED USE:

The Arctic Front Cryoballoon provides an efficient approach to pulmonary vein isolation (PVI). It creates circumferential lesions, isolating each pulmonary vein with minimal energy applications, delivering consistent and repeatable results.

The 2AF284 isolate the pulmonary veins for the treatment of atrial fibrillation.

The 4FC12 FlexCath Advance sheath and 2035U Umbilical cable work with the cryo catheters.

The 2AF234 isolate the pulmonary veins for treatment of atrial fibrillation. Smaller size than 2AF284.

The 203CX Umbilical coaxial cable

The 990063-020 20mm mapping catheter

3. UNIQUE CHARACTERISTICS THAT LIMIT AVAILABILITY TO ONLY ONE SOURCE, WITH THE REASON NO OTHER SUPPLIES OR SERVICES CAN BE USED:

The Arctic Front Advance System is the only cryoballoon system approved in the U.S. for the treatment of paroxysmal atrial fibrillation and in Europe for treatment of atrial fibrillation.

4. REASON THAT SUGGESTED SOURCE IS THE ONLY SOURCE, WHICH CAN PROVIDE THE SUPPLIES OR SERVICES:

Medtronic is the only manufacturer of the Arctic Front Advance System. The item(s) is(are) used with existing equipment and the equipment will only operate with the particular item(s). By not purchasing the item(s), additional cost to the government will occur. Clinical staff has been trained and are familiar with the proper use of the required item(s).

5. DESCRIPTION OF MARKET RESEARCH CONDUCTED AND RESULTS OR STATEMENT WHY IT WAS NOT CONDUCTED:

Medtronic has been the sole source for these products for the Arctic Front Advance System in the Pittsburgh VA. Market research was conducted by a FPDS, NAC Website and Google. Results from FPDS website show that Medtronic is the only contractor who can provide this item.

6. Contracting Officer's Certification: *Purchase is approved in accordance with FAR13.106-1(b). I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief. Note: COs are required to make a determination of price reasonableness IAW FAR 13.106-3. See the [Commercial Supply and Service SOP](#) for Price Reasonableness templates.*

Signature: _____

Name: AMANDA SAUNDERS

Title: Contracting Officer

Facility: NCO4

Date:

Signature: _____

Name:

Title: Branch Chief, Hybrid 2

Facility: NCO4

Date:

