

MEPNN Supplier Scouting Opportunity Synopsis

Section 1: General Information

Scouting Number	2024-345
Item to be Scouted	Probe Medical Device Assembly
Days to be scouted	30
Response Due By	12/07/2024
Description	Looking for a contract manufacturer. Initially, requester/client would provide the components; over time, the contract manufacturer would supply the components.
Notify Requester Immediately	
State item to be used in	Georgia

Section 2: Technical Information

Type of supplier being sought	Manufacturer
Reason	New product startup
Describe the manufacturing processes (elaborate to provide as much detail as possible)	Soldering and micro soldering. Pouch sealing and sterile barrier systems. ISO Class 7 Clean Room. Appropriate certifications for building human-use medical devices. Long-distance routing of very small gauge insulated electrical wiring through small lumens. Medical-grade adhesive bonding. Laser Welding.
Provide dimensions / size / tolerances / performance specifications for the item	See attached drawings
List required materials needed to make the product, including materials of product components	See attached drawings
Are there applicable certification requirements?	Yes
Certification(s) required	ISO 13485
Are there applicable regulations?	Yes
Details	FDA 21 CFR Part 820 - use of current Good Manufacturing Practice (cGMP) in production of the device.
Are there any other standards, requirements, etc.?	No
NAICS 1	
NAICS 2	
Additional Technical Comments	

Section 4: Business Information

Estimated potential business volume	YR 1 = 200. YR 2 = 500. YR 3 - 750. NOTE: this opportunity is to gauge interest and capability. A more complete set of drawings and specifications would be provided after required NDAs are completed.
Estimated target price / unit cost information (if unavailable explain)	To be determined in negotiations/Open
When is it needed by?	January, 2025 (earliest)

Describe packaging requirements	Best available. Delivered undamaged. Specifics discussed in negotiation.
Where will this item be shipped?	Atlanta Georgia The contract manufacturer ships (after sterilization) back to the client, not to the end customer (typically a hospital or medical center).

Additional Comments

Is there other information you would like to include?

2

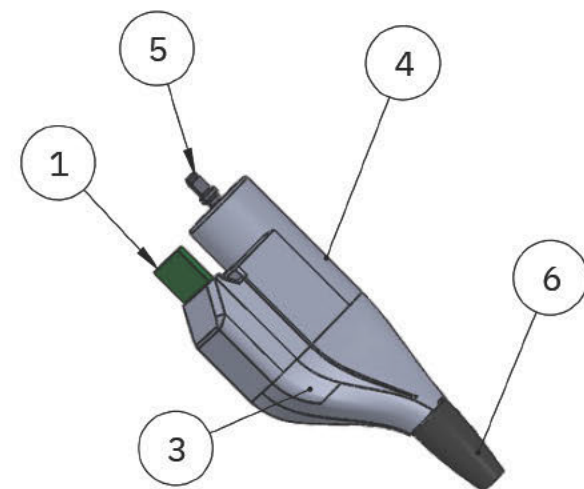
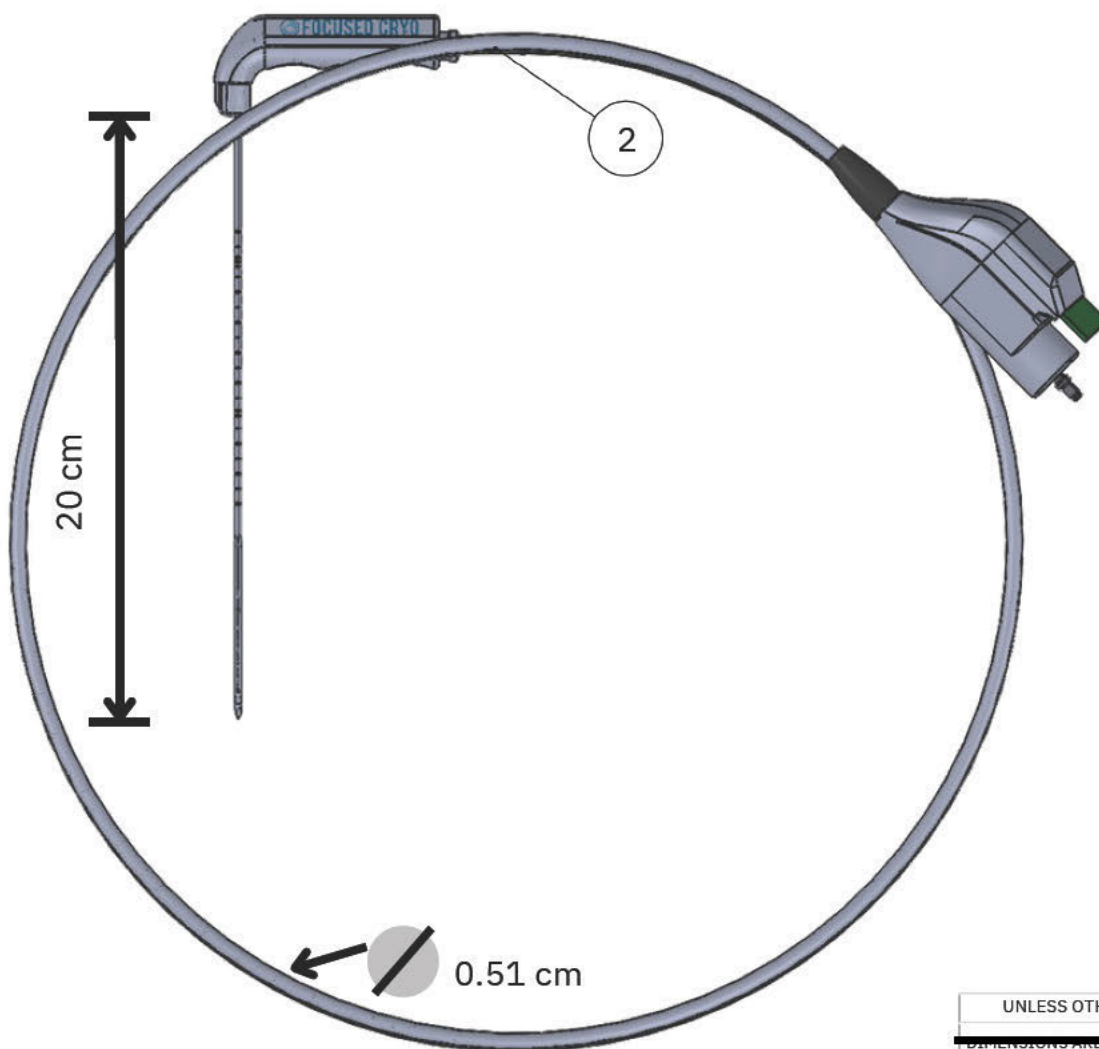
1

REV1 PN

LHRSA-09

B

B



A

A

UNLESS OTHERWISE SPECIFIED:

~~DIMENSIONS ARE IN INCHES~~

TOLERANCES:

FRACTIONAL 1/16th

ANGULAR: MACH 0±5 BEND ± 0.5

TWO PLACE DECIMAL ± 0.01

THREE PLACE DECIMAL ± 0

0.00

INTERPRET GEOMETRIC 5

TOLERANCING PER: 3RD ANGLE PROJECTION

MATERIAL

SEE TABLE

DO NOT SCALE DRAWING

TITLE:

PROBE PROXIMAL
SUBASSEMBLY

SIZEDWG. NO.

A

1109 02

SCALE: 1:2WEIGHT:

REV

SHEET 2 OF 2

PROPRIETARY AND CONFIDENTIAL

THE INFORMATION CONTAINED IN THIS
DRAWING IS THE SOLE PROPERTY OF
~~FOCUSED CRYO~~. ANY REPRODUCTION
IN PART OR AS A WHOLE WITHOUT THE
WRITTEN PERMISSION OF FOCUSED
CRYO IS PROHIBITED.

2

1

[REDACTED]	Subassembly Specification Probe Proximal Subassembly	[REDACTED] 1109
		Revision: 02 DCR-00132 Eff Date: [REDACTED]

Custom

Off-the-Shelf

Item No.	Part Requirements	
P1	Description	Probe Proximal Subassembly
P2	Material	N/A
P3	Dimensions	Refer to drawing [REDACTED] 1109 (Rev02) for full component dimensions
P4	Color	N/A
P5	Expiration Date	N/A
P6	Packaging	N/A
P7	Rev1 Part Number	LHRSA-09

Item No.	Documentation Requirements	
D1	Certifications	<input type="checkbox"/> None <input type="checkbox"/> Material Safety Data Sheet <input type="checkbox"/> Certificate of Analysis <input type="checkbox"/> Material Certification <input type="checkbox"/> Certification of Compliance/Conformance <input type="checkbox"/> RoHS Compliance <input checked="" type="checkbox"/> Other: LHR
D2	Documentation	Lot History Record
D3	Inspection	See manufacturer work instruction WI-09-028 for inspection steps.

Item No.	Storage Requirements	
S1	Environmental	Cool, dry indoor environment
S2	Handling	Handle with care

Document Change History

Version	Description and Reason for Change
02	Added cover sheet.
01	Initial release.



2

1

ITEM NO.	PART DESCRIPTION	PART NUMBER	QTY.
1	EDGE CARD SUBASSEMBLY	[REDACTED]-1107	1
2	PROBE DISTAL SUBASSEMBLY	[REDACTED]-1108	1
3	TERMINATION HOUSING A	[REDACTED]-1022	1
4	TERMINATION HOUSING B	[REDACTED]-1023	1
5	GAS CONNECTOR	[REDACTED]-1024	1
6	STRAIN RELIEF	[REDACTED]-1057	1
7	SRA #99 FLUX	[REDACTED]-1068	AR
8	LOCTITE 3979	[REDACTED]-1072	AR
9	LOCTITE 3922	[REDACTED]-1041	AR
10	SOLDER	[REDACTED]-1027	AR
11	ALPHA 90 FLUX	[REDACTED]-1035	AR

REV1 PN	LHRSA-09
---------	----------

B

B

A

A

NOTES:

1. LOAD TERMINATION HOUSING A AND ADHERE GAS CONNECTOR.
2. SOLDER 20 WIRES TO EDGE CARD.
3. ATTACH EDGE CARD TO COUPLER BOTTOM.
4. ADHERE AND HEAT SHRINK CONNECTOR TOP AND BOTTOM.
5. ASSEMBLY TO TAKE PLACE IN CLEAN ENVIRONMENT.

PROPRIETARY AND CONFIDENTIAL
 THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF [REDACTED]. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF FOCUSED CRYO IS PROHIBITED.

UNLESS OTHERWISE SPECIFIED:		[REDACTED]	
DIMENSIONS ARE IN INCHES TOLERANCES: FRACTIONAL ± 1/16th ANGULAR: MACH ± 0.5 BEND ± 0.5 TWO PLACE DECIMAL ± 0.010 THREE PLACE DECIMAL ± 0.005		TITLE: PROBE PROXIMAL SUBASSEMBLY	
INTERPRET GEOMETRIC TOLERANCING PER: 3RD ANGLE PROJECTION	MATERIAL SEE TABLE	SIZE A	D [REDACTED] 1109 REV 02
DO NOT SCALE DRAWING		SCALE: 1:2	WEIGHT: SHEET 1 OF 2

2

1

2

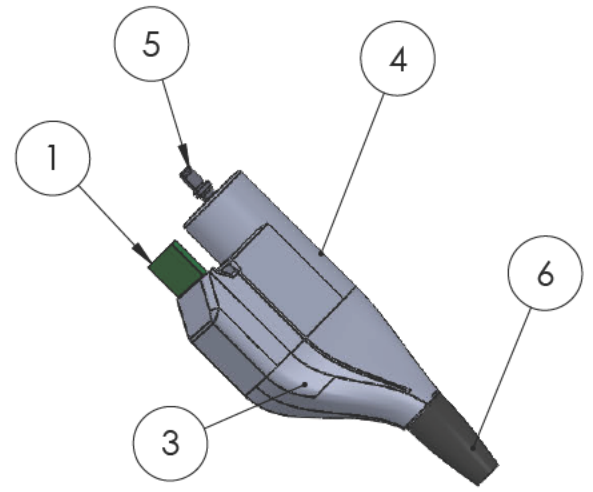
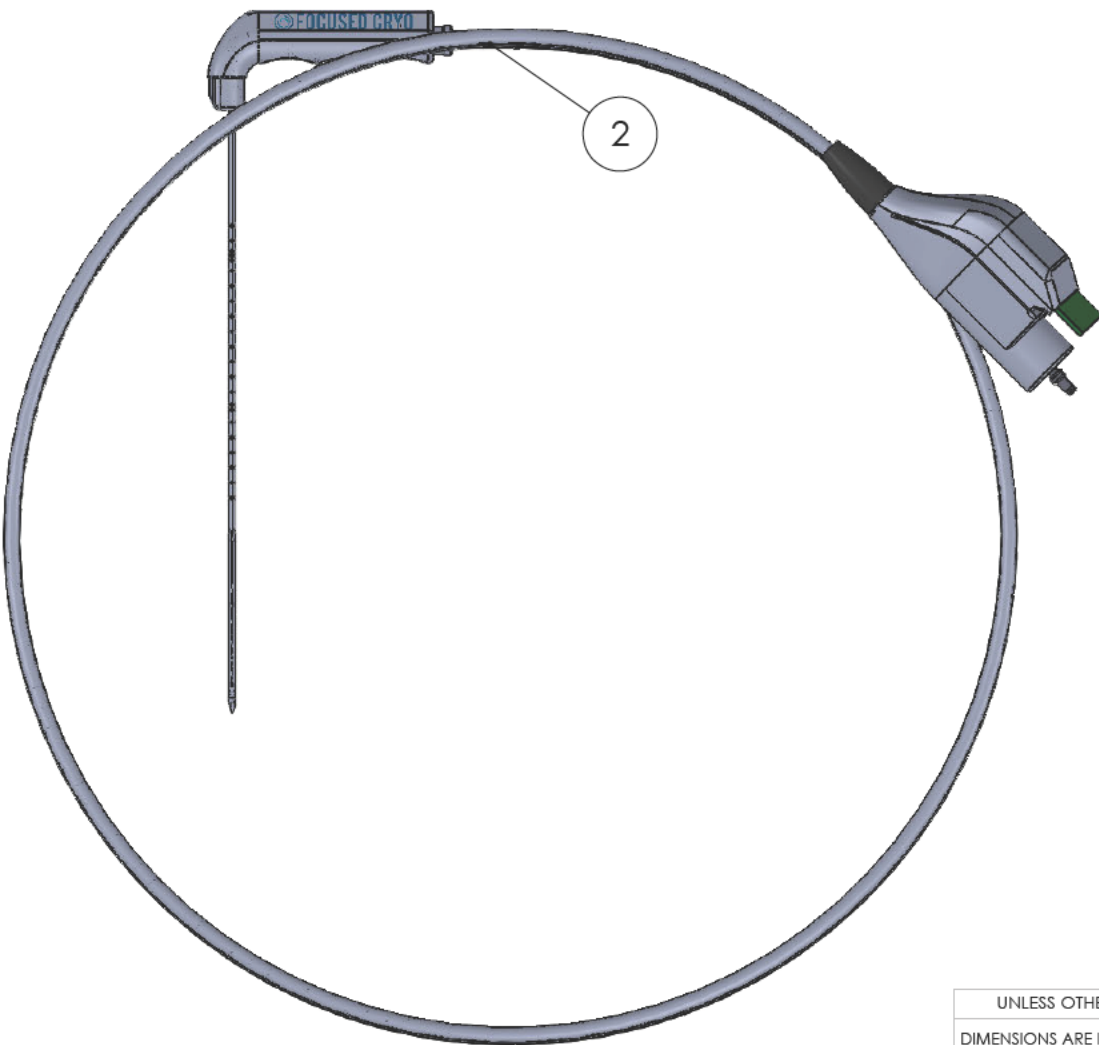
1

REV1 PN

LHRSA-09

B

B



A

A

UNLESS OTHERWISE SPECIFIED:
 DIMENSIONS ARE IN INCHES
 TOLERANCES:
 FRACTIONAL $\pm 1/16$ th
 ANGULAR: MACH ± 0.5 BEND ± 0.5
 TWO PLACE DECIMAL ± 0.010
 THREE PLACE DECIMAL ± 0.005

[REDACTED]

TITLE:
**PROBE PROXIMAL
 SUBASSEMBLY**

PROPRIETARY AND CONFIDENTIAL
 THE INFORMATION CONTAINED IN THIS
 DRAWING IS THE SOLE PROPERTY OF
 [REDACTED]. ANY REPRODUCTION
 IN PART OR AS A WHOLE WITHOUT THE
 WRITTEN PERMISSION OF FOCUSED
 CRYO IS PROHIBITED.

INTERPRET GEOMETRIC
 TOLERANCING PER: 3RD ANGLE PROJECTION
 MATERIAL
 SEE TABLE

SIZE D [REDACTED] 1109 REV 02
A

DO NOT SCALE DRAWING

SCALE: 1:2 WEIGHT: SHEET 2 OF 2

2

1