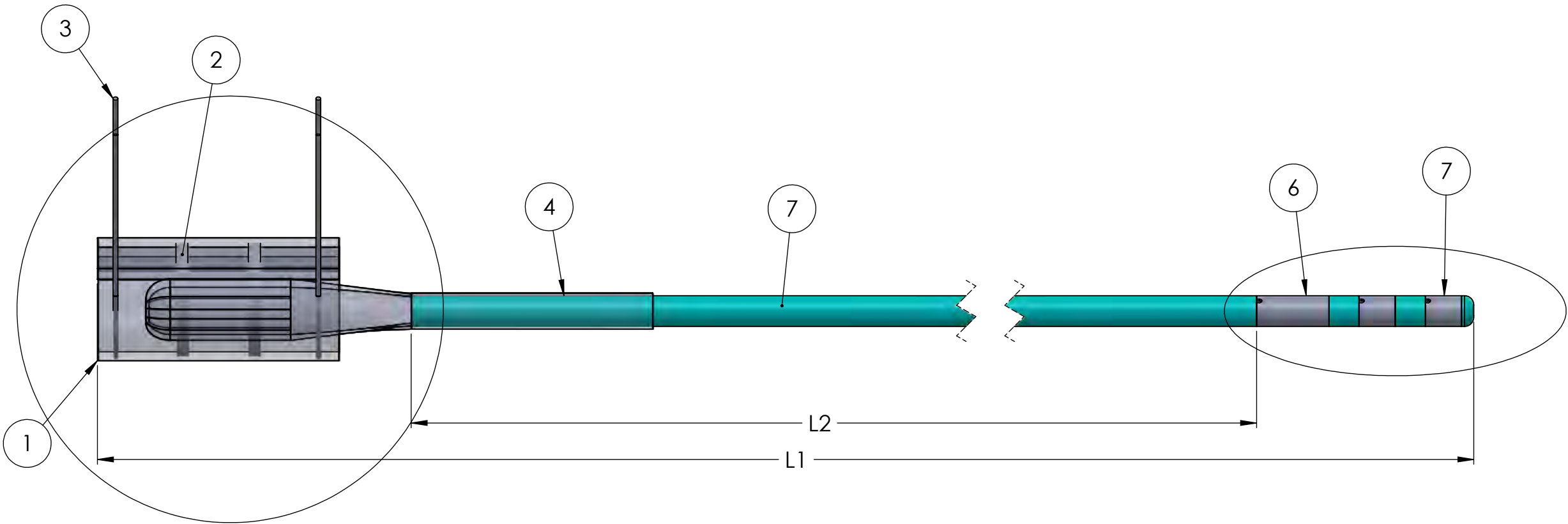


4				3				2				1			
ITEM NO.	PART NUMBER	DESCRIPTION	QTY.					REVISIONS							
1	6168	Silicone Sheet 10mm x 20mm	2					REV.	ECO	DESCRIPTION	DRAWN BY	DATE			
2	6169	Cuff Electrode - 18mm	2					0.1		INITIAL RELEASE	F. ROBERTS	11 MAR 2023			
3	6170	Suture - 35mm	2												
4	6171	Silicone Tubing	13 mm												
5	6089	3 mm Contact	1												
6	6090	1.5 mm Contact	2												
7	6085	Outer Tubing	L2												
8	6153	PEEK Inner Tubing	10 mm												
9	7065	Loctite M-11FL Urethane Adhesive	A/R												
10	7073	Silicone Adhesive, MED-2000	A/R												
12	5036	2 Filar Coil	L1												

DRAFT

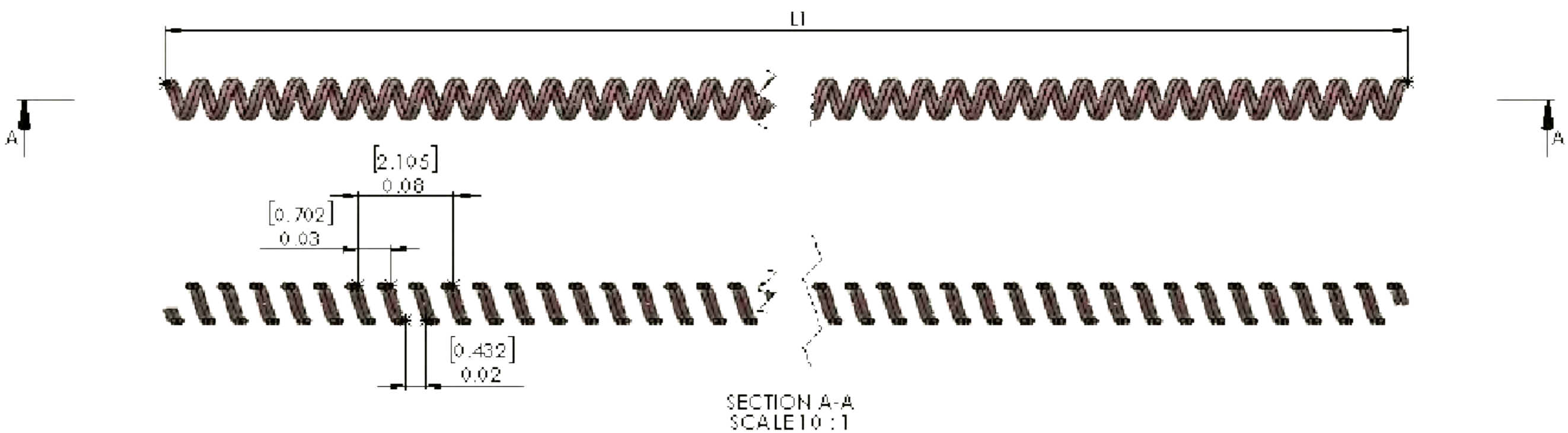


- NOTES:
1. L1 = 15cm - 100cm
 2. L2 = 12.8cm - 97.8cm

Next Assembly

UNLESS OTHERWISE SPECIFIED:				MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES				TITLE:	
TOLERANCES:				Bipolar Cuff	
FRACTIONAL ±					
ANGULAR: MACH ±.5					
BEND ±					
TWO PLACE DECIMAL ±[0.20] / .008					
THREE PLACE DECIMAL ±[0.100] / .004					
DO NOT SCALE DRAWING					
PROPRIETARY AND CONFIDENTIAL					
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.				SIZE	REV
				B	0.1
				DWG. NO.	
				3018	
				SCALE: 5:1	SHEET 1 OF 6

DRAFT

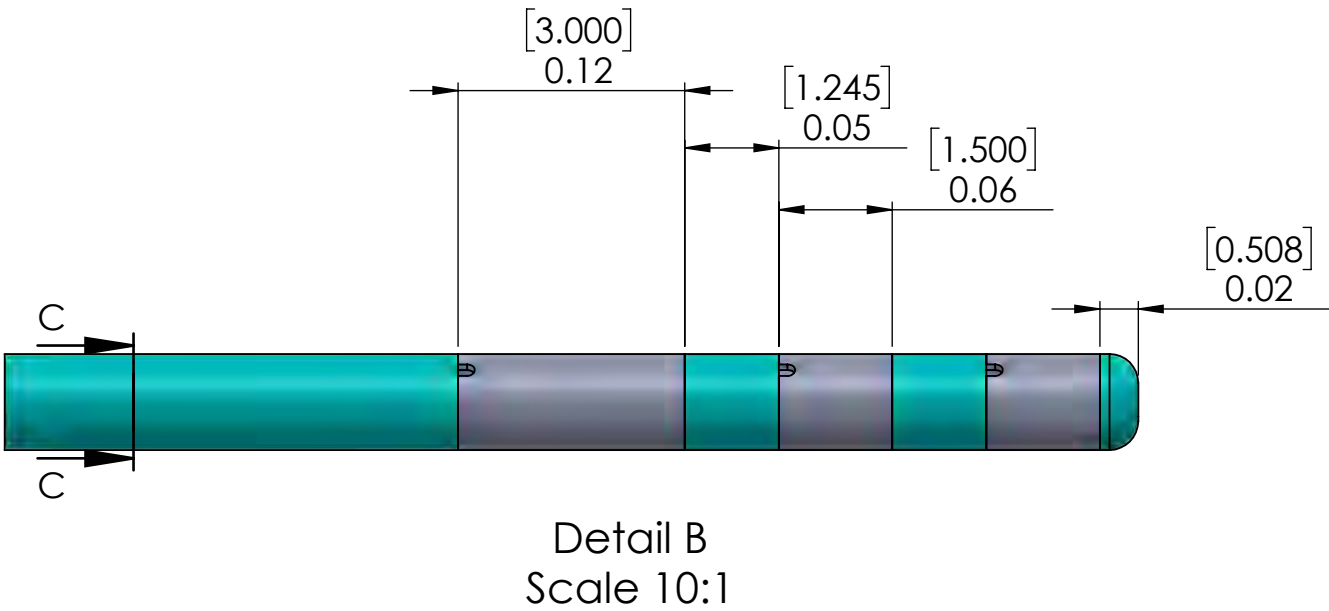
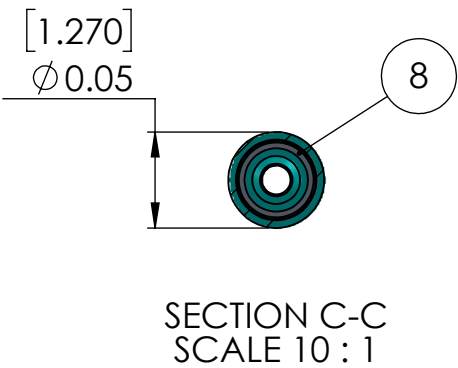


Two Filar Coil

Next Assembly

UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE: Bipolar Cuff	
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.	SIZE B	DWG. NO. 3018	REV 0.1
	SCALE: 10:1		SHEET 2 OF 6

DRAFT

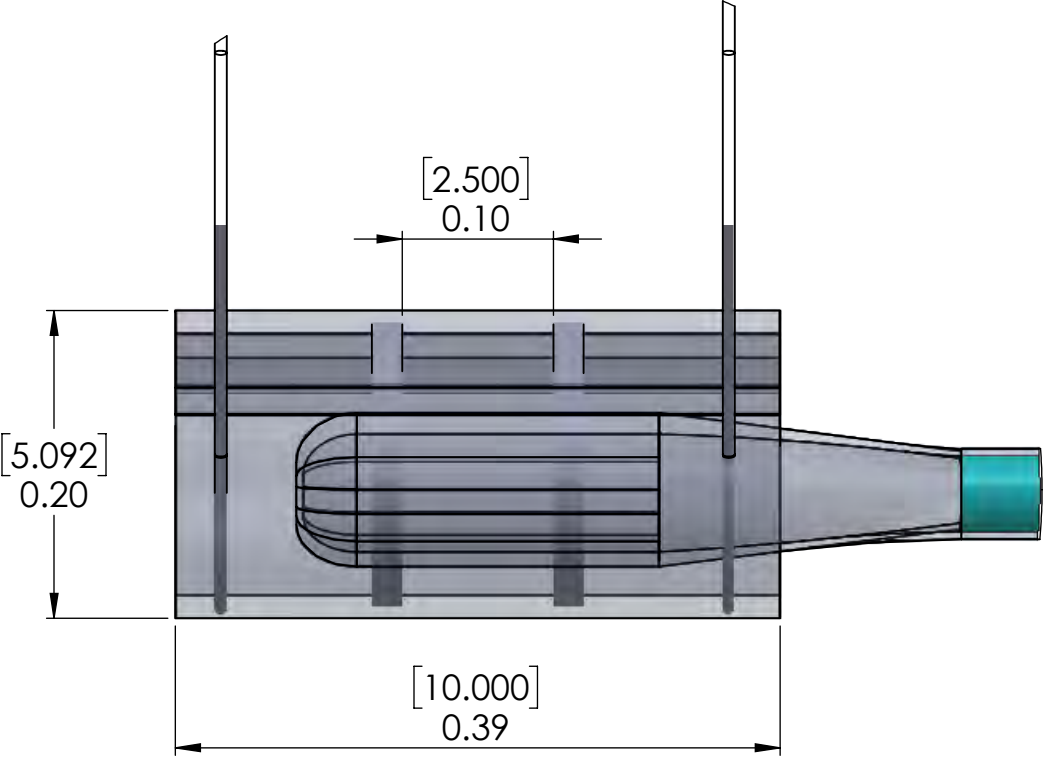
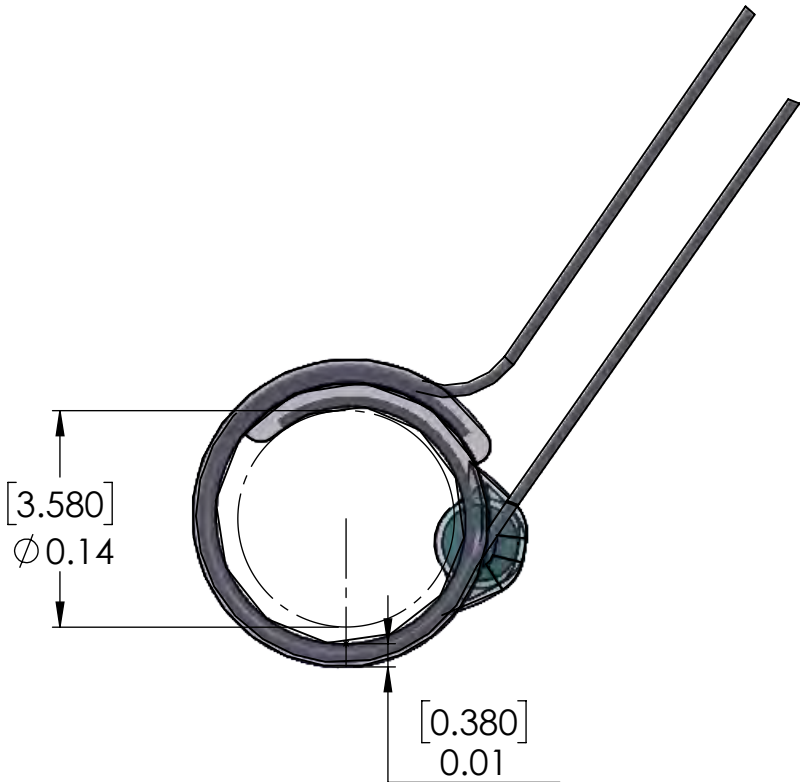


Proximal End

Next Assembly

UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE:	
		Bipolar Cuff	
		SIZE	DWG. NO.
		B	3018
PROPRIETARY AND CONFIDENTIAL		REV	0.1
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SCALE: 10:1	
		SHEET 3 OF 6	

DRAFT

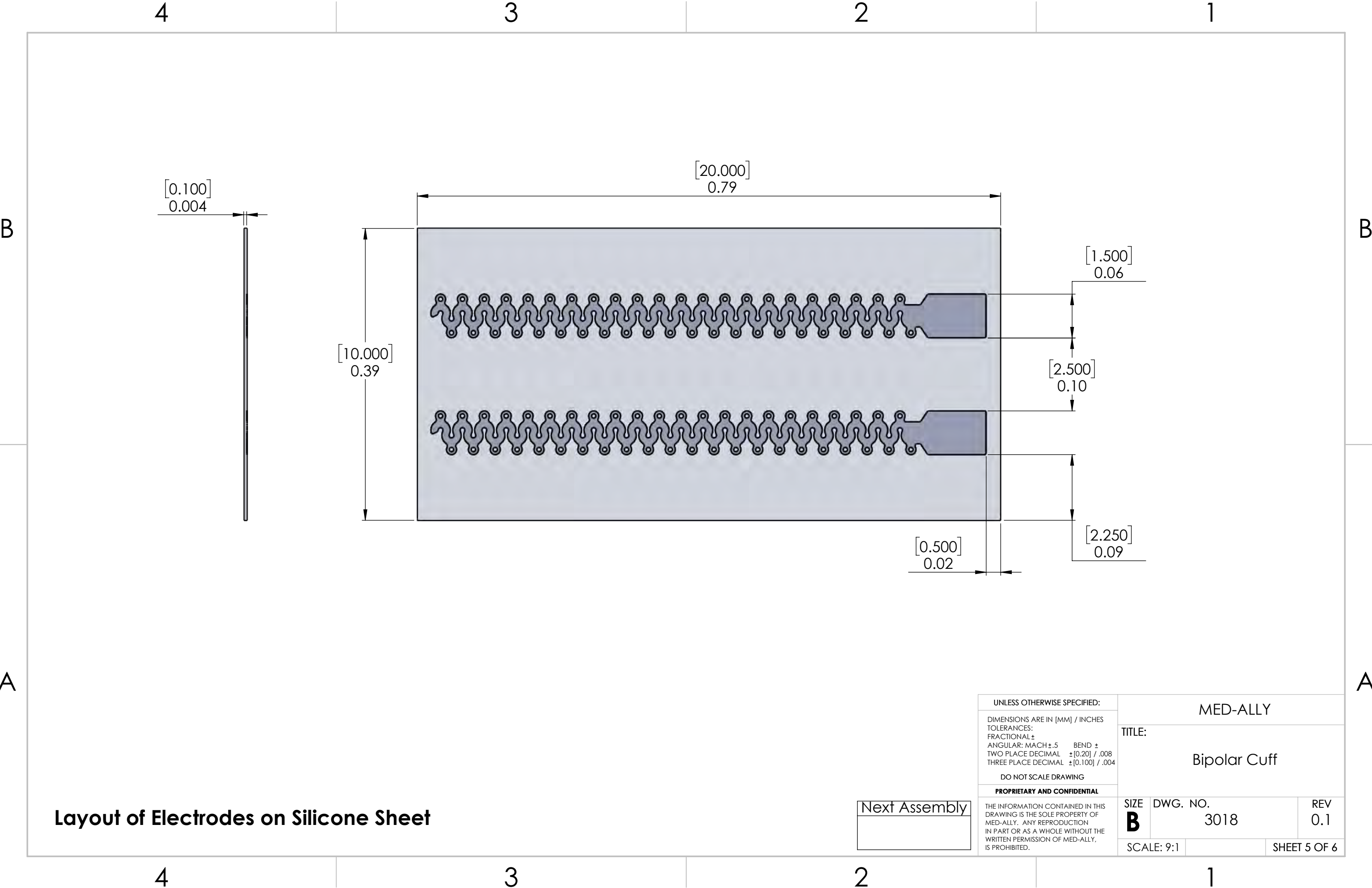


DETAIL B
SCALE 8 : 1

Distal End

Next Assembly

UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004		TITLE: Bipolar Cuff	
DO NOT SCALE DRAWING			
PROPRIETARY AND CONFIDENTIAL			
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.	SIZE B	DWG. NO. 3018	REV 0.1
	SCALE: 8:1		SHEET 4 OF 6

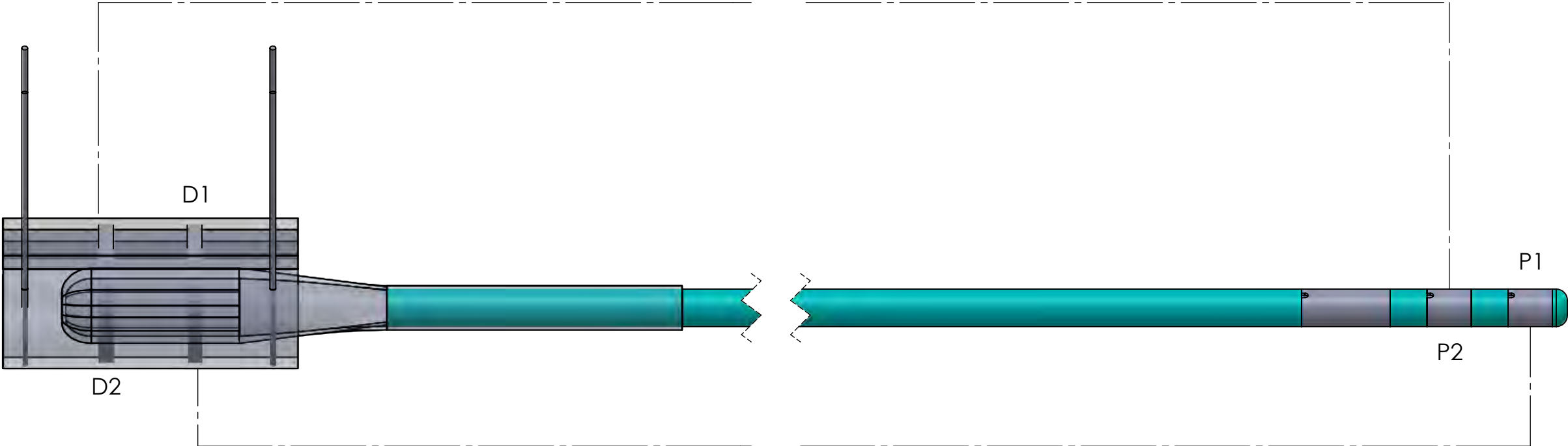


Layout of Electrodes on Silicone Sheet

Next Assembly

UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE:	
		Bipolar Cuff	
		SIZE	DWG. NO.
		B	3018
PROPRIETARY AND CONFIDENTIAL		REV	0.1
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SCALE: 9:1	SHEET 5 OF 6

DRAFT



Proximal Wire Connection	Distal Wire Connection
P1	D1
P2	D2

Next Assembly

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES				
TOLERANCES:				
FRACTIONAL ±				
ANGULAR: MACH ±.5 BEND ±		TITLE: Bipolar Cuff		
TWO PLACE DECIMAL ±[0.20] / .008				
THREE PLACE DECIMAL ±[0.100] / .004				
DO NOT SCALE DRAWING				
PROPRIETARY AND CONFIDENTIAL				
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SIZE	DWG. NO.	REV
		B	3018	0.1
		SCALE: 5:1		SHEET 6 OF 6

4

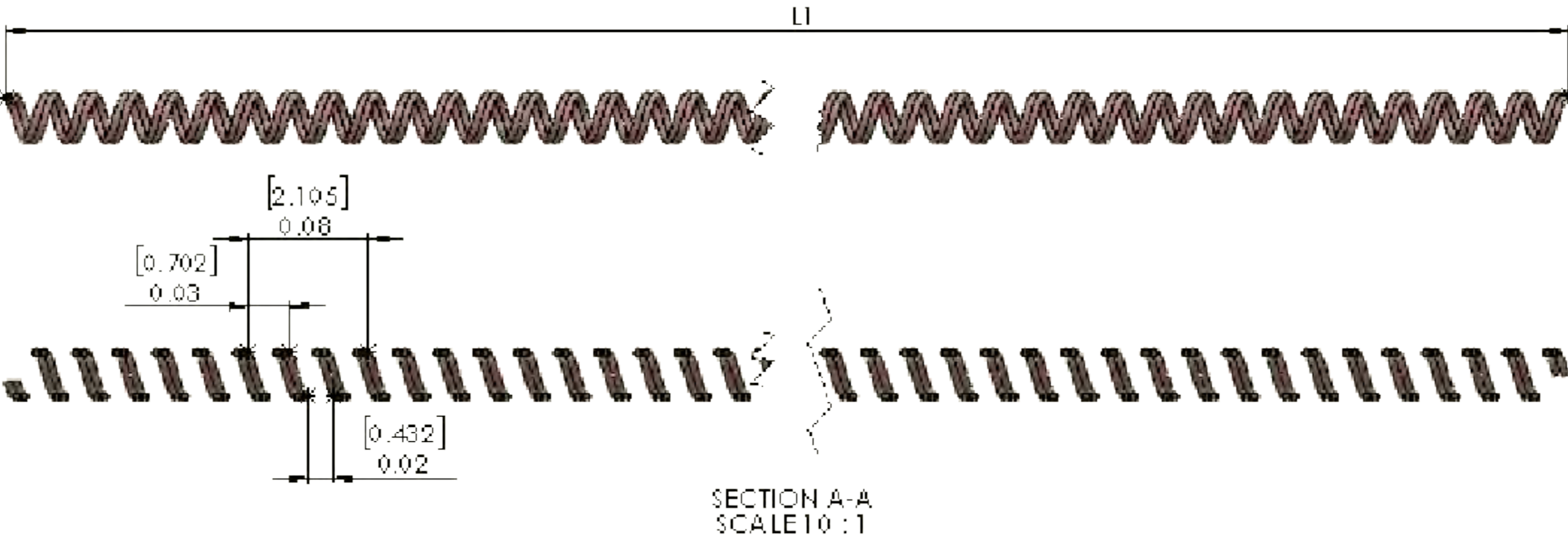
3

2

1

B

B



DRAFT

Next Assembly

UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE: ECG Lead	
PROPRIETARY AND CONFIDENTIAL		SIZE B	REV 0.1
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		DWG. NO. 3020	SHEET 2 OF 5

4

3

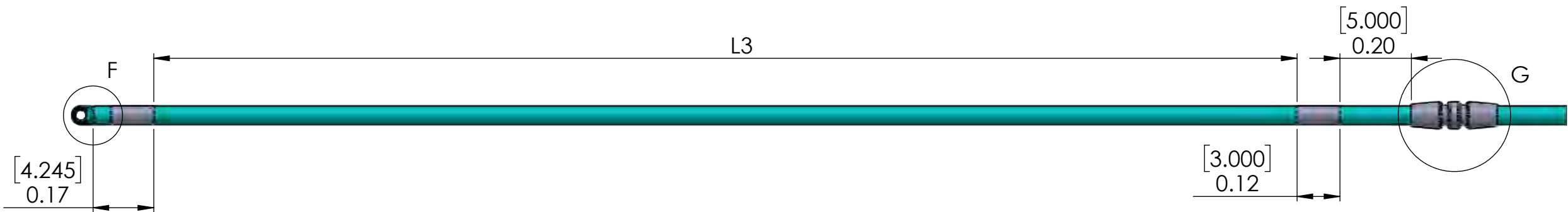
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1

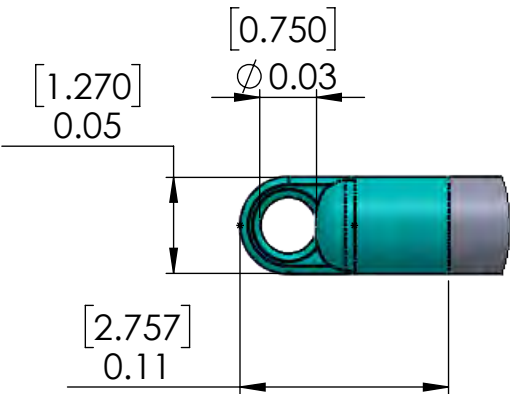
A

A

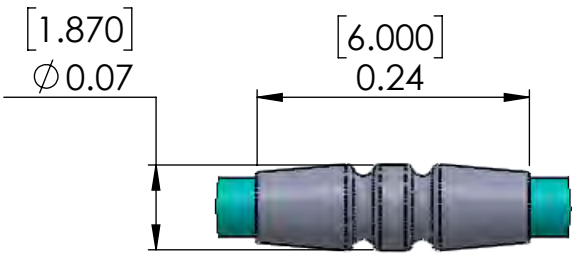
DRAFT



Detail A
Scale 3:1



DETAIL F
SCALE 10 : 1



DETAIL G
SCALE 6 : 1

DISTAL END

Next Assembly

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES				
TOLERANCES:				
FRACTIONAL ±				
ANGULAR: MACH ±.5 BEND ±		TITLE: ECG Lead		
TWO PLACE DECIMAL ±[0.20] / .008				
THREE PLACE DECIMAL ±[0.100] / .004				
DO NOT SCALE DRAWING				
PROPRIETARY AND CONFIDENTIAL				
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SIZE	DWG. NO.	REV
		B	3020	0.1
		SCALE: 3:1		SHEET 3 OF 5

4

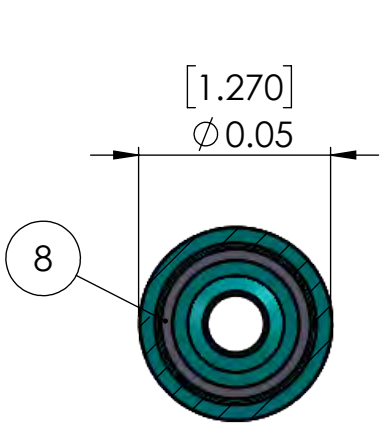
3

2

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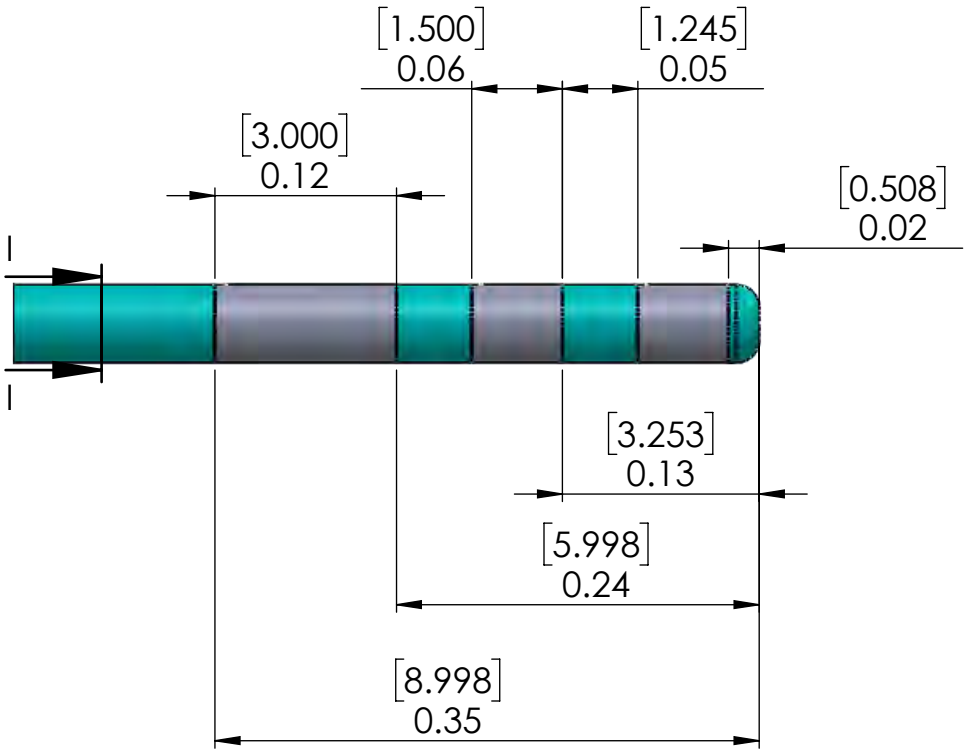
B

B



SECTION I-I
SCALE 20 : 1

DRAFT



Detail B
Scale 8:1

Proximal End

4

3

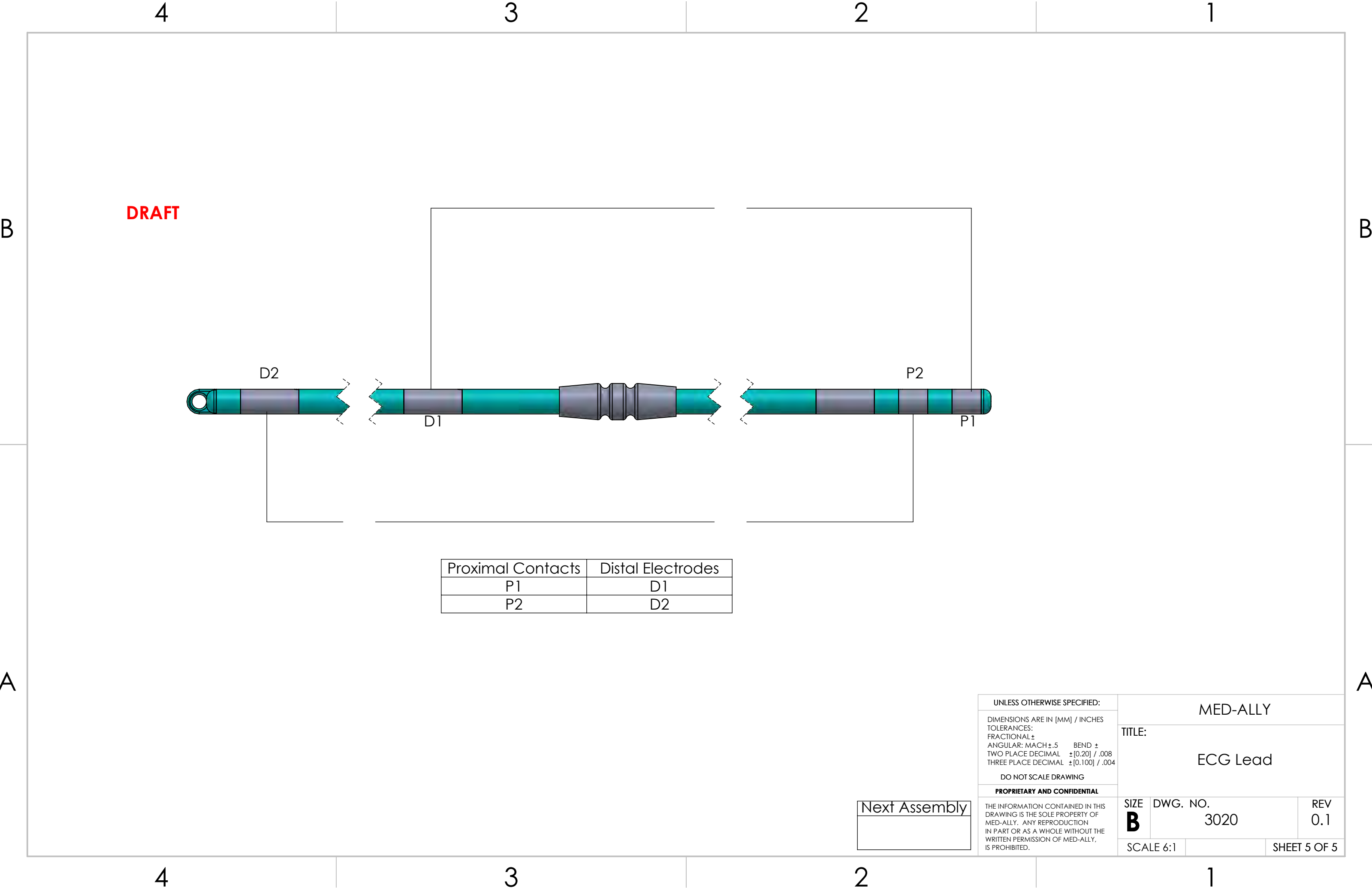
2

1

A

A

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE:		
		ECG Lead		
		PROPRIETARY AND CONFIDENTIAL		
		THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		
Next Assembly		SIZE B	DWG. NO. 3020	REV 0.1
		SCALE: 8:1		SHEET 4 OF 5



UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN [MM] / INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ±.5 BEND ±
TWO PLACE DECIMAL ±[0.20] / .008
THREE PLACE DECIMAL ±[0.100] / .004

DO NOT SCALE DRAWING

PROPRIETARY AND CONFIDENTIAL

THE INFORMATION CONTAINED IN THIS
DRAWING IS THE SOLE PROPERTY OF
MED-ALLY. ANY REPRODUCTION
IN PART OR AS A WHOLE WITHOUT THE
WRITTEN PERMISSION OF MED-ALLY,
IS PROHIBITED.

MED-ALLY

TITLE:
ECG Lead

SIZE
B

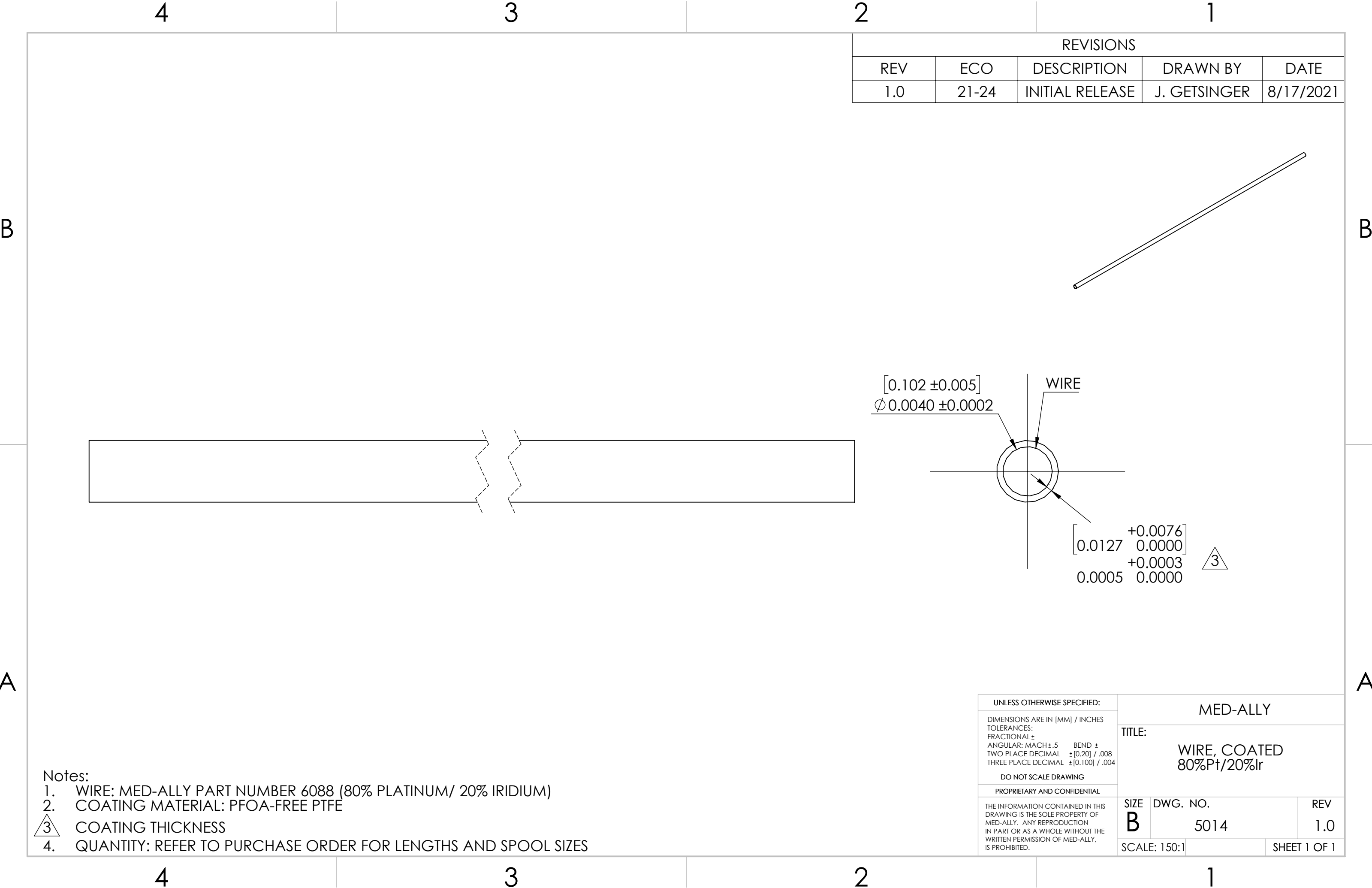
DWG. NO.
3020

REV
0.1

SCALE 6:1

SHEET 5 OF 5

Next Assembly

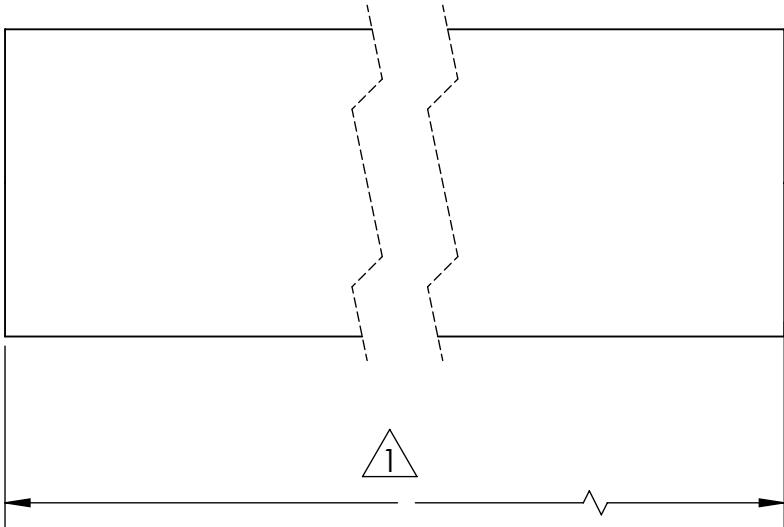


REVISIONS				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	21-24	INITIAL RELEASE	J. GETSINGER	8/17/2021

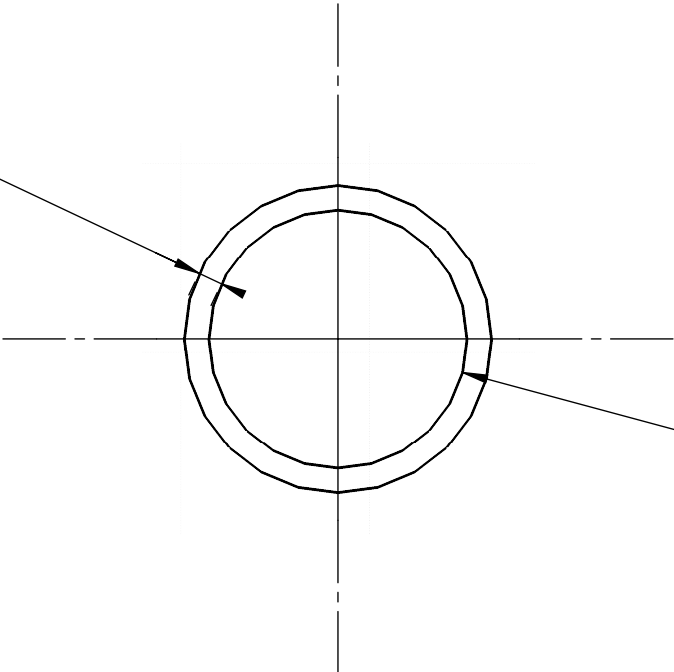
- Notes:
1. WIRE: MED-ALLY PART NUMBER 6088 (80% PLATINUM/ 20% IRIIDIUM)
 2. COATING MATERIAL: PFOA-FREE PTFE
 3. COATING THICKNESS
 4. QUANTITY: REFER TO PURCHASE ORDER FOR LENGTHS AND SPOOL SIZES

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE: WIRE, COATED 80%Pt/20%Ir		
		SIZE	DWG. NO.	REV
		B	5014	1.0
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SCALE: 150:1		SHEET 1 OF 1

REVISIONS				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	21-24	INITIAL RELEASE	J. GETSINGER	12AUG21
2.0	21-45	REMOVED MATERIAL FROM NAME, CHANGED ID FROM 0.039 TO 0.042 AND DIMENSIONED WALL INSTEAD OF OD	J.GETSINGER	6DEC21



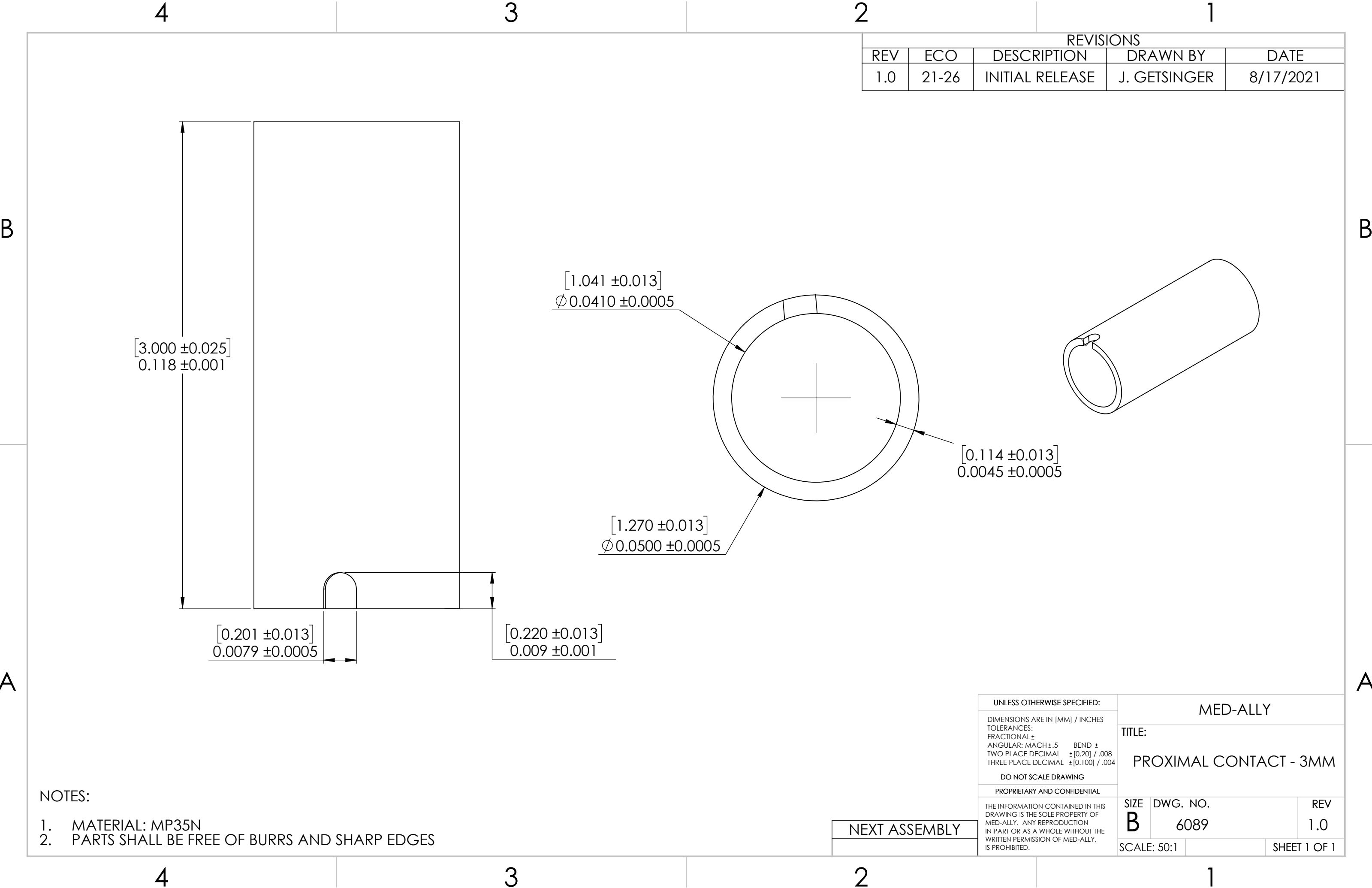
[0.10±0.04]
.0040±.0015



[1.07±0.04]
Ø.0420±.0015

- NOTES:
- 1 REFER TO TUBING LENGTH SPECIFIED ON PURCHASE ORDER
 2. MATERIAL: POLYURETHANE, 55D

UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING PROPRIETARY AND CONFIDENTIAL THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		TITLE: OUTER TUBING	
		SIZE B	REV 2.0
		DWG. NO. 6085	DATE 12AUG21
		SCALE: 32:1	SHEET 1 OF 1



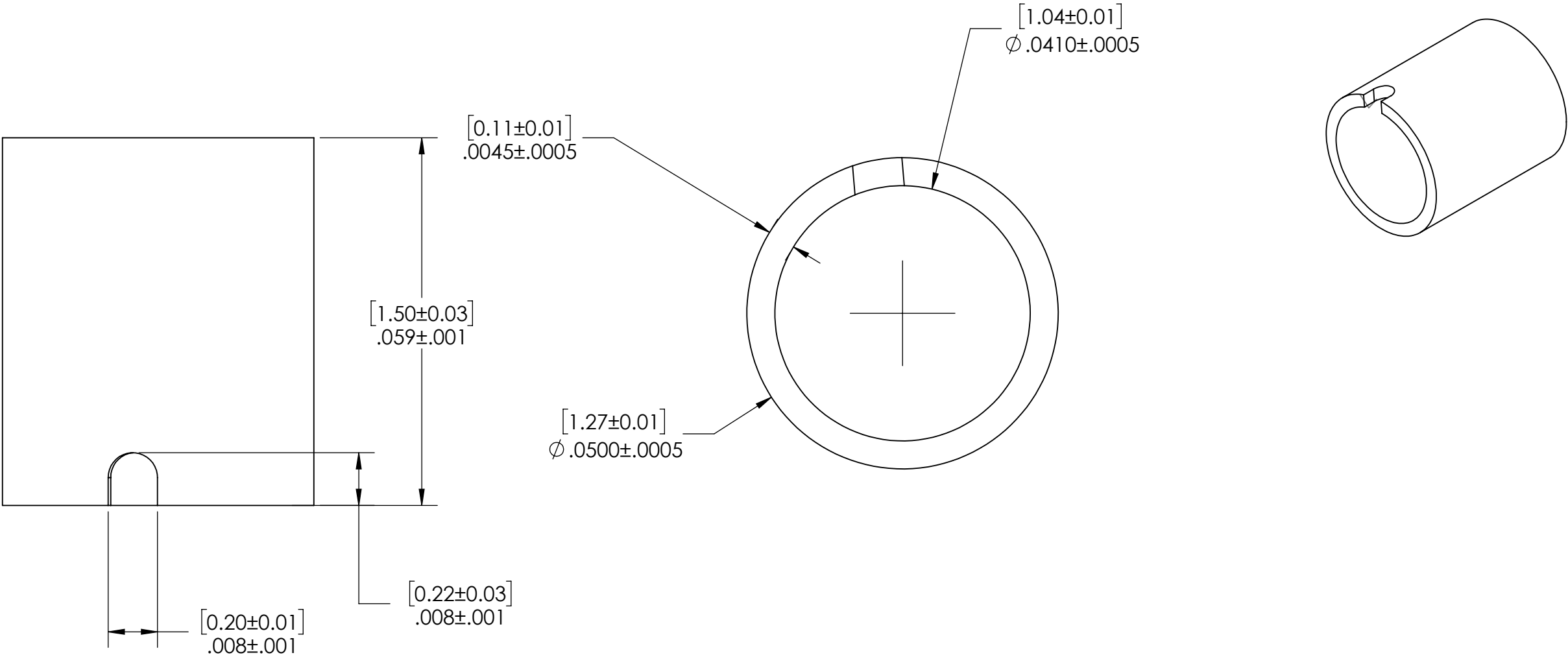
REVISIONS				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	21-26	INITIAL RELEASE	J. GETSINGER	8/17/2021

NOTES:

- MATERIAL: MP35N
- PARTS SHALL BE FREE OF BURRS AND SHARP EDGES

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE:		
		PROXIMAL CONTACT - 3MM		
		PROPRIETARY AND CONFIDENTIAL		
		THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		
NEXT ASSEMBLY		SIZE	DWG. NO.	REV
		B	6089	1.0
		SCALE: 50:1		SHEET 1 OF 1

REVISIONS				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	21-26	INITIAL RELEASE	J. GETSINGER	8/17/2021
2.0	21-37	RE-RELEASE	J. GETSINGER	10/13/2021

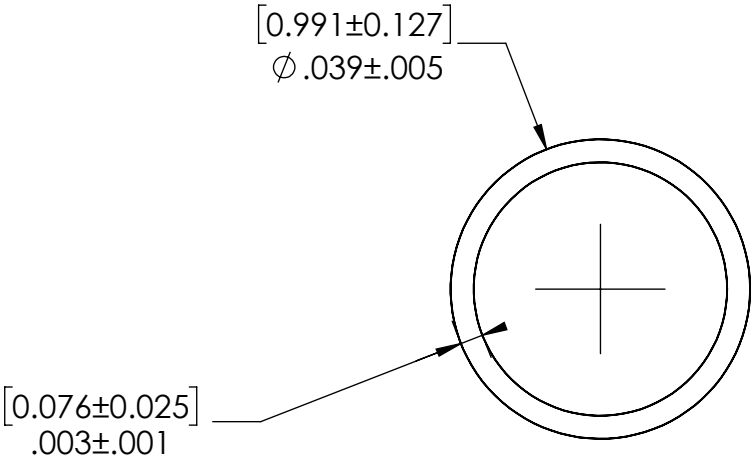
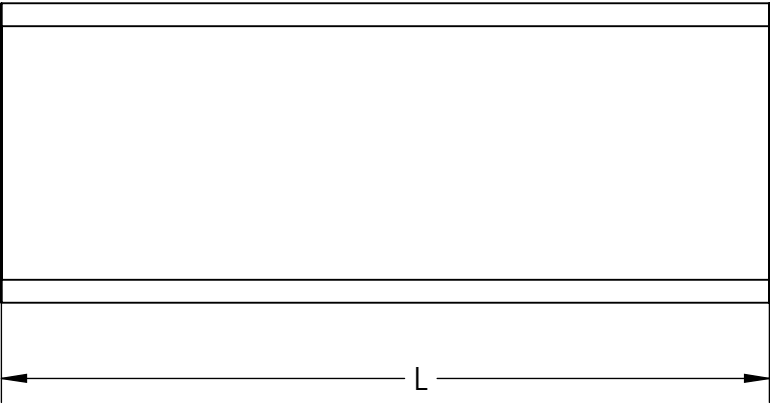
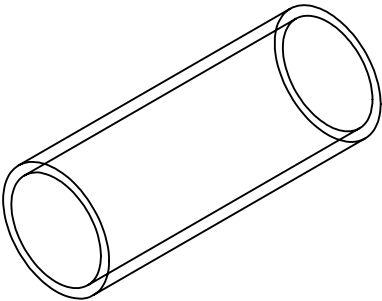


- NOTES:
- MATERIAL: MP35N
 - PARTS SHALL BE FREE OF BURRS AND SHARP EDGES

NEXT ASSEMBLY

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE: PROXIMAL CONTACT - 1.5MM		
		PROPRIETARY AND CONFIDENTIAL		
		THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		
		SIZE B	DWG. NO. 6090	REV 2.0
SCALE: 50:1		SHEET 1 OF 1		

Revisions				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	22-28	INITIAL RELEASE	J. GETSINGER	4NOV22



- NOTES:
- MATERIAL: PEEK
 - LENGTH (L) WILL BE DISTINGUISHED ON PO

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE: PEEK SINGLE LUMEN TUBE		
		SIZE	DWG. NO.	REV
		B	6153	1.0
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SCALE: 40:1		SHEET 1 OF 1

4

3

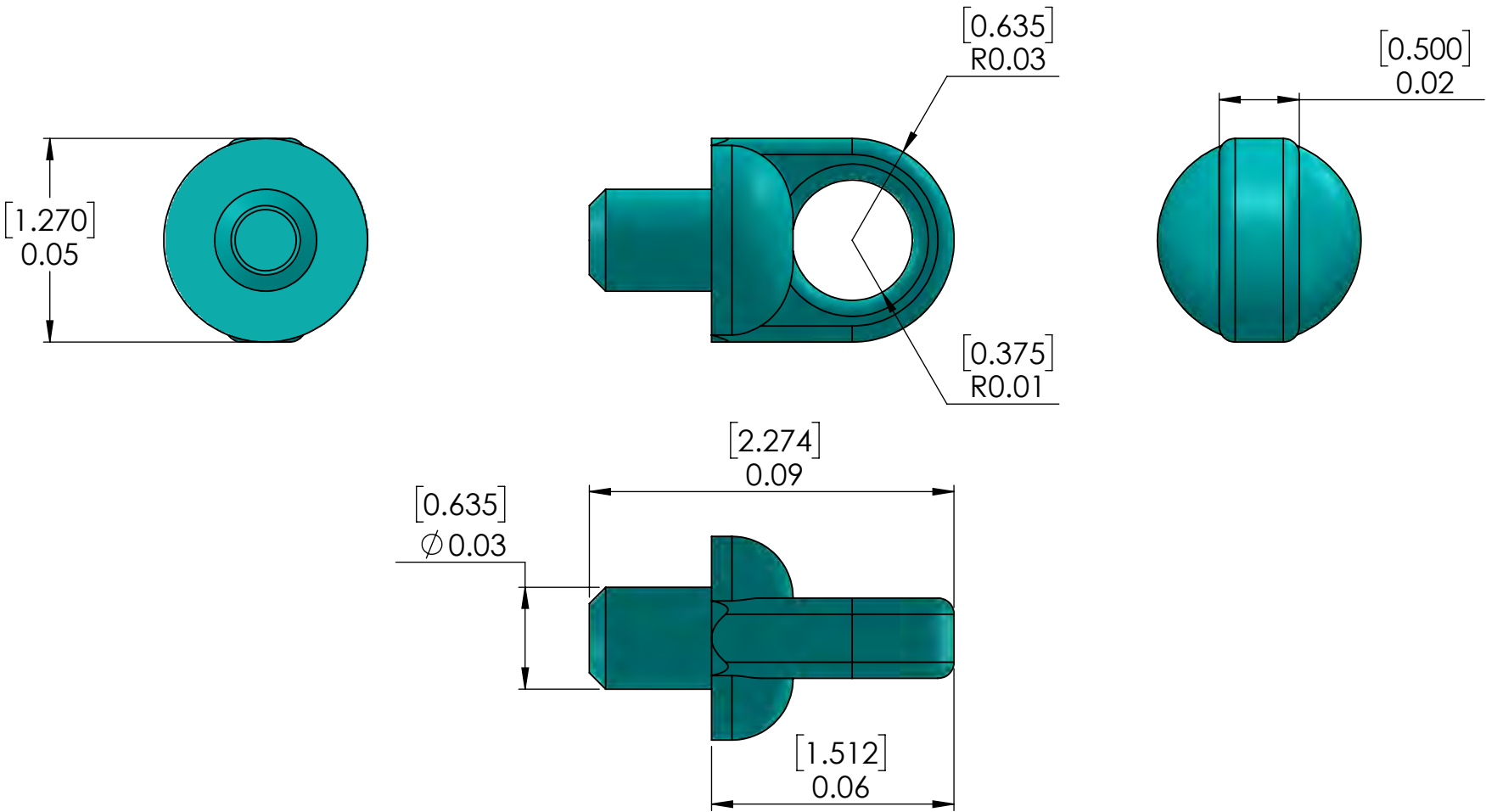
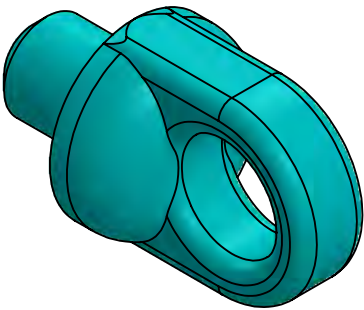
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1

REVISIONS

REV.	ECO	DESCRIPTION	DRAWN BY	DATE
0.1			F. ROBERTS	24 MAR 2023

DRAFT



Model Number: 8275

Next Assembly
3020

UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES			
TOLERANCES:			
FRACTIONAL ±			
ANGULAR: MACH ±.5 BEND ±			
TWO PLACE DECIMAL ±[0.20] / .008			
THREE PLACE DECIMAL ±[0.100] / .004			
DO NOT SCALE DRAWING			
PROPRIETARY AND CONFIDENTIAL		TITLE: Distal Suture Tip	
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.			
SIZE	DWG. NO.	REV	
B	6175	0.1	
SCALE: 5:1		SHEET 1 OF 1	

4

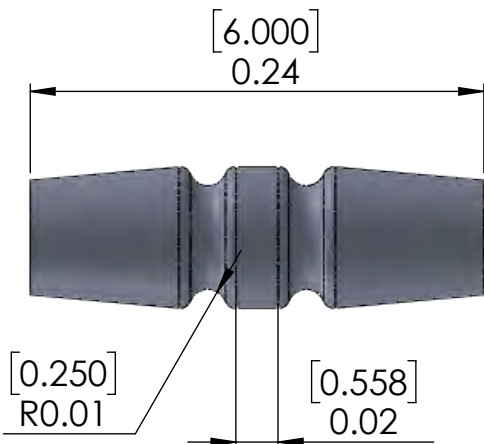
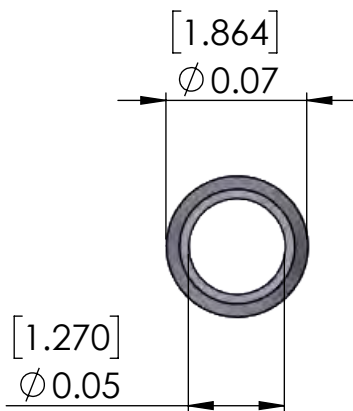
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2

1

REVISIONS				
REV.	ECO	DESCRIPTION	DRAWN BY	DATE
0.1		INITIAL RELEASE	F.ROBERTS	24 MAR 2023

DRAFT



Model Number: 8276

Next Assembly
3020

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE:		
		Suture Sleeve		
		SIZE	DWG. NO.	REV
		B	6176	0.1
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SCALE: 5:1		SHEET 1 OF 1

4

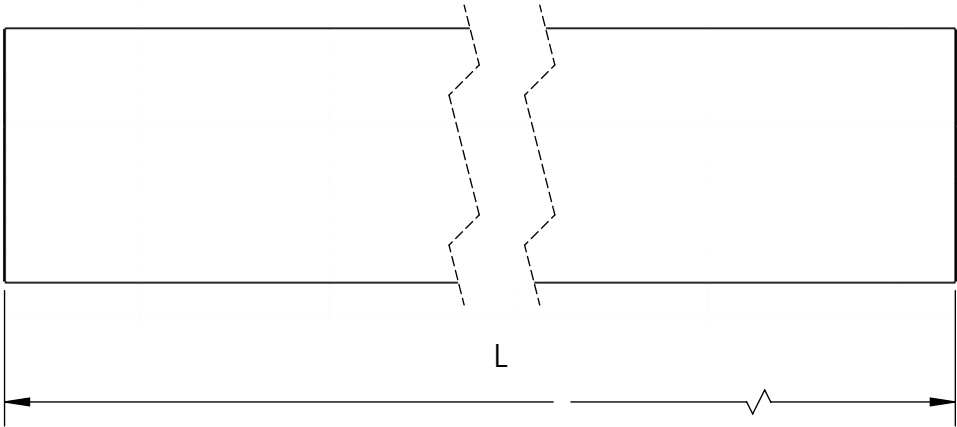
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2

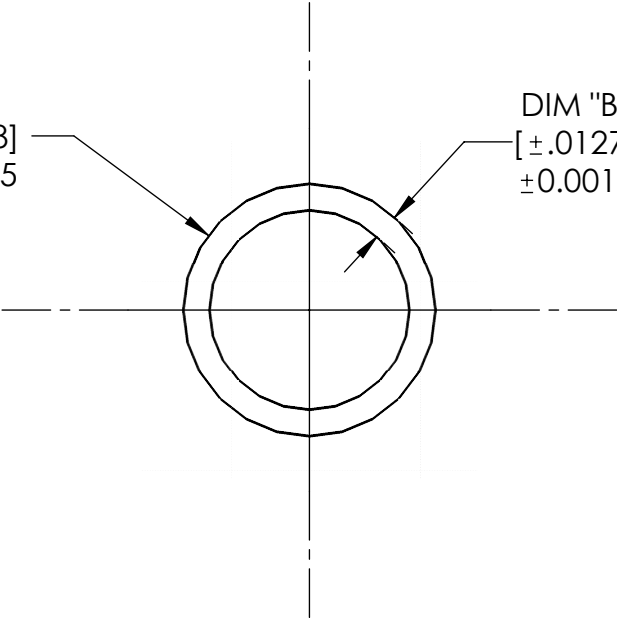
1

REVISIONS				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	21-24	INITIAL RELEASE	J. GETSINGER	12AUG21
2.0	21-31	ADDED TUBE 6084-4	J. GETSINGER	7SEPT21
3.0	21-45	REMOVED MATERIAL FROM NAME AND DIMENSIONED WALL INSTEAD OF OD	J. GETSINGER	6DEC21

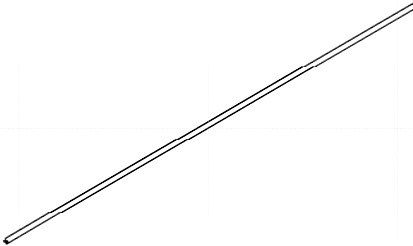
B



DIM "A"
[$\varnothing \pm 0.038$]
 $\varnothing \pm 0.0015$



DIM "B"
[$\pm .0127$]
 ± 0.0015



B

TABLE A			
PART NUMBER	DIM "A"	DIM "B"	LENGTH (L)
6084-1	0.041 [1.04]	0.0043 [.12]	SPECIFIED IN PO
6084-2	0.052 [1.32]	0.0065 [0.17]	SPECIFIED IN PO
6084-3	0.051 [1.30]	0.0093 [0.24]	SPECIFIED IN PO
6084-4	0.039 [0.99]	0.0033 [0.083]	SPECIFIED IN PO

Notes:
1. MATERIAL: POLYURETHANE, 80A

UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL \pm ANGULAR: MACH $\pm .5$ BEND \pm TWO PLACE DECIMAL $\pm [0.20]$ / .008 THREE PLACE DECIMAL $\pm [0.100]$ / .004 DO NOT SCALE DRAWING		TITLE: INNER TUBING	
		PROPRIETARY AND CONFIDENTIAL	
		THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.	
		SIZE B	DWG. NO. 6084
SCALE: 32:1		REV 3.0	SHEET 1 OF 1

A

A

4

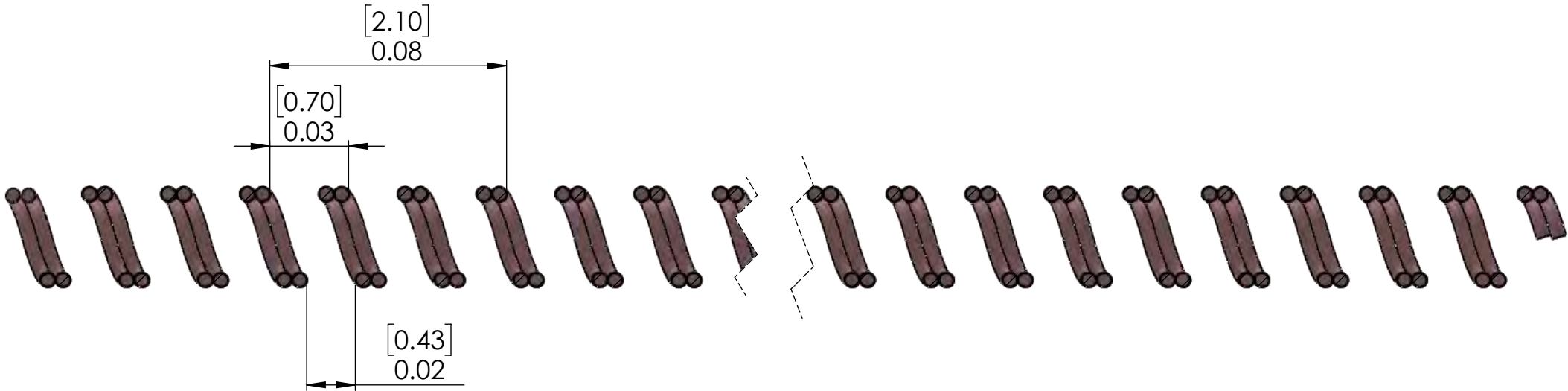
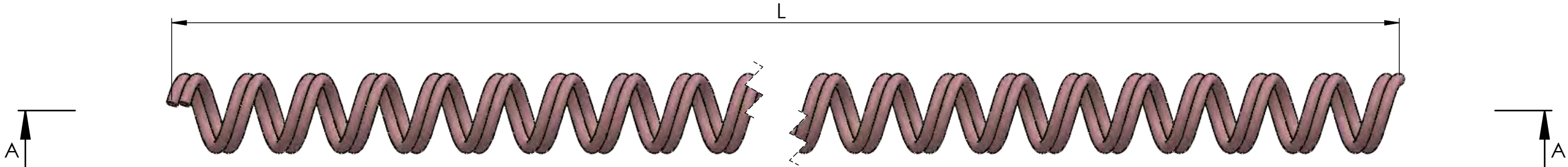
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2

1

DRAFT

REVISIONS				
REV.	ECO	DESCRIPTION	DRAWN BY	DATE
0.1		INITIAL RELEASE	F. ROBERTS	9 JUN 2023



SECTION A-A
SCALE 20 : 1

NOTES:
1. LENGTH L DEFINED IN HIGHER ASSEMBLIES

Next Assembly

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL \pm ANGULAR: MACH $\pm .5$ BEND \pm TWO PLACE DECIMAL $\pm [0.20] / .008$ THREE PLACE DECIMAL $\pm [0.100] / .004$ DO NOT SCALE DRAWING		TITLE:		
		2 Filar Coil		
		SIZE	DWG. NO.	REV
		B	5036	0.1
PROPRIETARY AND CONFIDENTIAL		SCALE: 5:1		
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.				SHEET 1 OF 1

4

3

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1

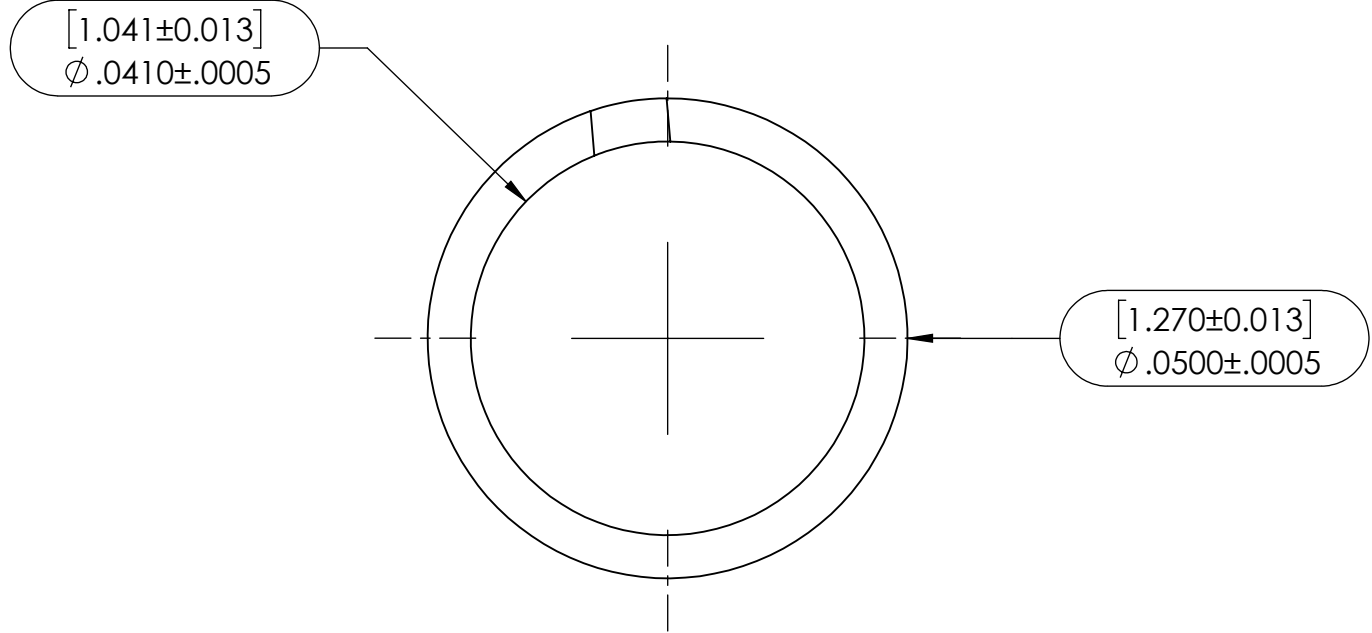
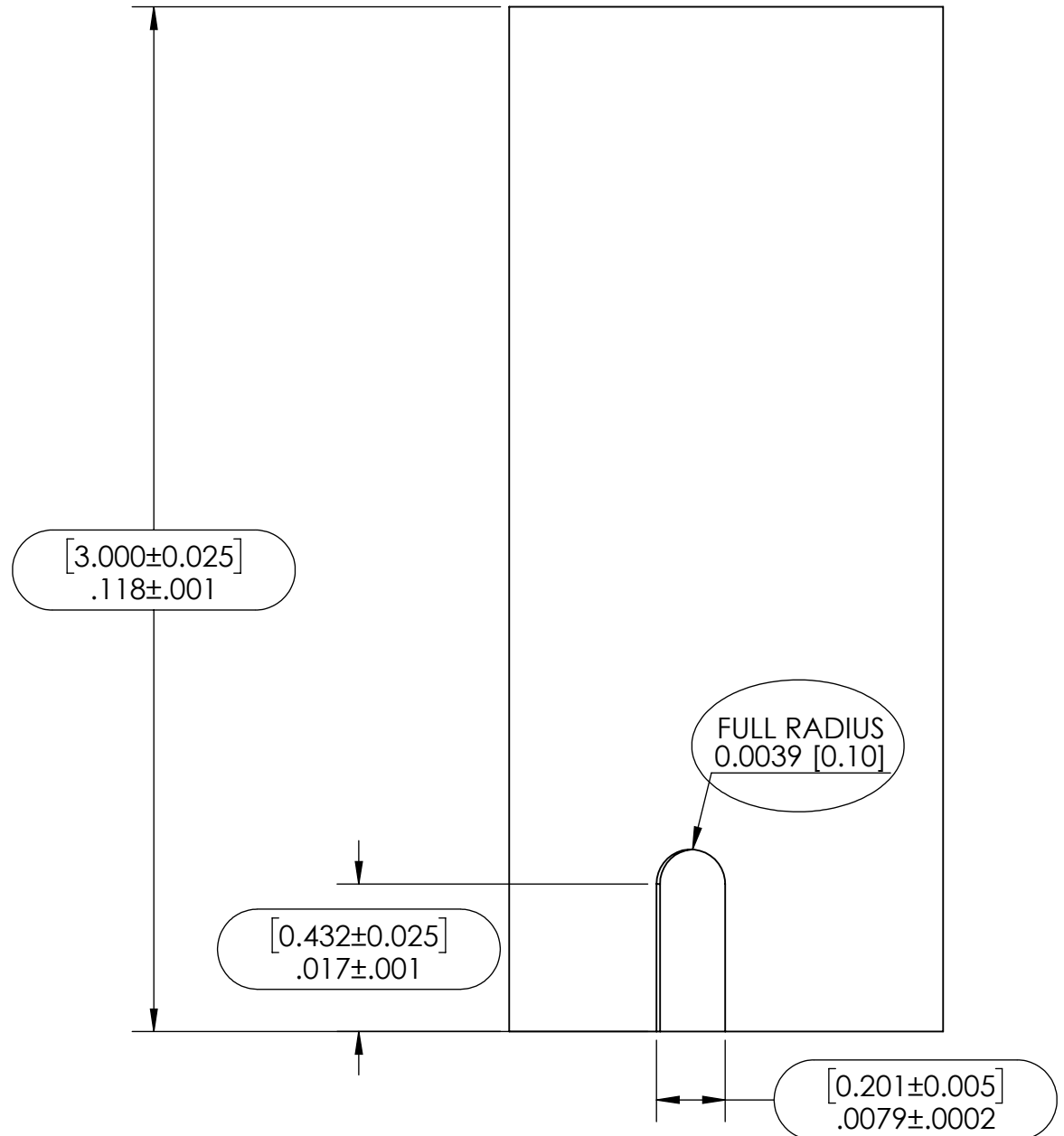
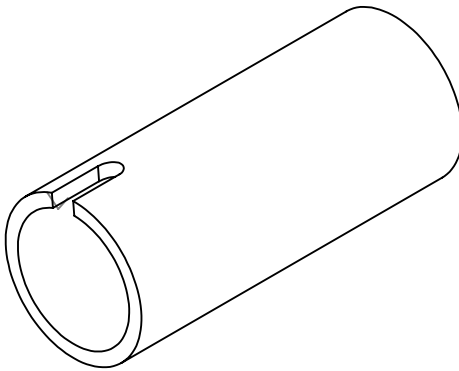
B

B

A

A


REVISIONS				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	21-22	INITIAL RELEASE	J. GETSINGER	7/30/21
2.0	21-37	RE-RELEASE	J. GETSINGER	10/13/2021



- NOTES:
- 1. MATERIAL: 90%Pt/10%Ir
 - 2. PARTS SHALL BE FREE OF BURRS AND SHARP EDGES
 - 3. SEE TABLE A FOR DIFFERENT LENGTHS OF ELECTRODES
 - 4. CRITICAL DIMENSIONS ARE CIRCLED

TABLE A	
PART NUMBER	LENGTHS
6081-3	0.118" [3 MM]
6081-1.5	0.059" [1.50 MM]

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING PROPRIETARY AND CONFIDENTIAL THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		TITLE: ELECTRODE		
		SIZE B	DWG. NO. 6081	REV 2.0
		SCALE: 50:1		SHEET 1 OF 1

	Drawing No:	7065	Revision:	1.0
	Part No:	7065	Created By:	J. Getsinger
	Part Description 1:	Loctite M-11FL		
	Part Description 2:	Urethane Adhesive		
Med-Ally,LLC 2040 Bushy Park Road, North Bldg 6 Goose Creek, SC 29445	Supplier Part No:	235029		
	Supplier Name:	R.S. Hughes/Henkel		
	Specification Control Drawing			

Rev	ECO Number	Description	Date
1.0	ECO 22-28	Initial Release	4Nov22



Technical Information

Agency Approvals / Certificates / Specifications	ISO 10993
Cure Type	Room Temperature (Ambient) Cure
Key Characteristics	Flexible: Highly Flexible, Peel Strength: High, Peel Strength: Viscosity: Low Viscosity
Number of Components	2 Part
Physical Form	Liquid
Shear Strength, Aluminum (etched)	1850.0 psi
Shear Strength, Steel (grit blasted)	160.0 psi
Substrates	Glass, Metal, Plastic
Mixed	
Color, Mixed	Clear; Ultra Clear
Resin	
Color, Resin	Clear
Hardener	
Color, Hardener	Clear

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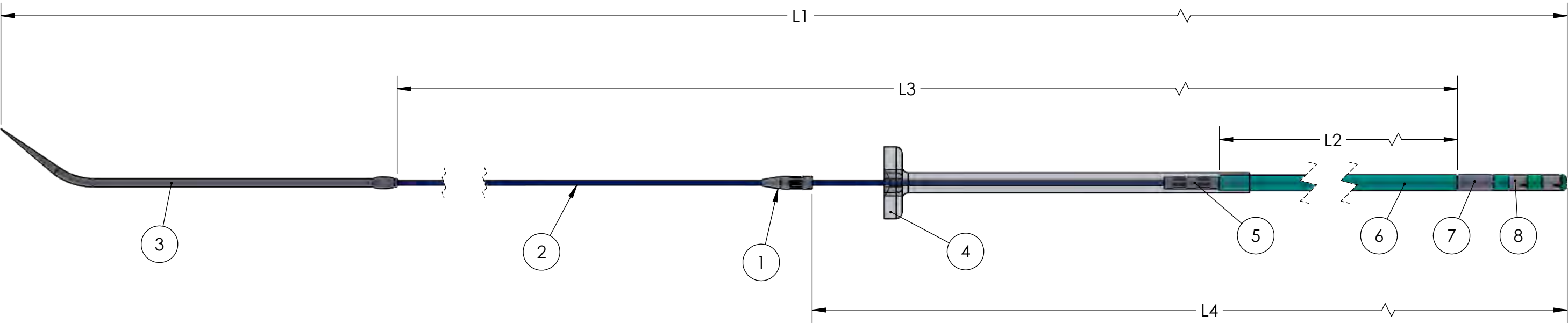
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1

REVISIONS

REV.	ECO	DESCRIPTION	DRAWN BY	DATE
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DRAFT



ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	6177	EMG Suture - Crimp	1
2	6178	Polypropylene Filament	L3
3	7085	EMG Suture - Needle	1
4	6179	Trumpet Anchor	1
5	6180	EMG Trumpet - Crimp	1
6	6085	Outer Tubing	L2
7	6089	Contact, Proximal, 3.00 mm	1
8	6090	Contact, Proximal, 1.50 mm	2
9	6153	PEEK Single Lumen Tube	10mm
10	5036	2 Filar Coil	L4
11	7065	Loctite M-11FL Urethane Adhesive	A/R
12	7073	Silicone Adhesive, MED-2000	A/R

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE: EMG Lead		
		PROPRIETARY AND CONFIDENTIAL		
		SIZE B	DWG. NO. 3021	REV 0.1
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SCALE: 5:1		SHEET 1 OF 5

Next Assembly

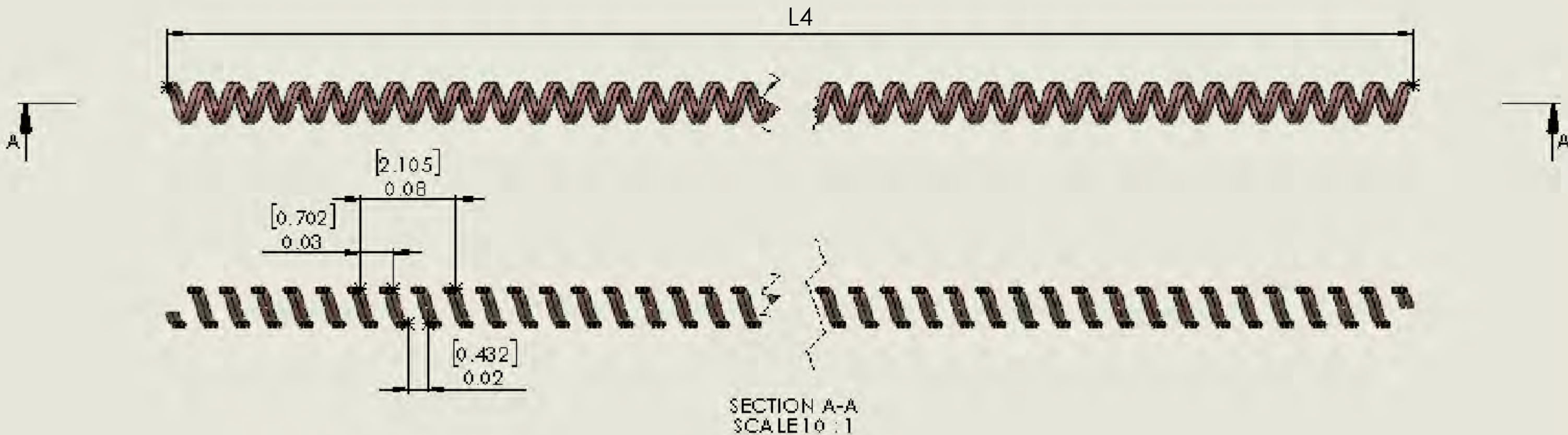
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UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004		TITLE: EMG Lead	
DO NOT SCALE DRAWING			
PROPRIETARY AND CONFIDENTIAL			
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SIZE B	REV 0.1
		DWG. NO. 3021	REV 0.1
		SCALE: 5:1	SHEET 2 OF 5

Next Assembly

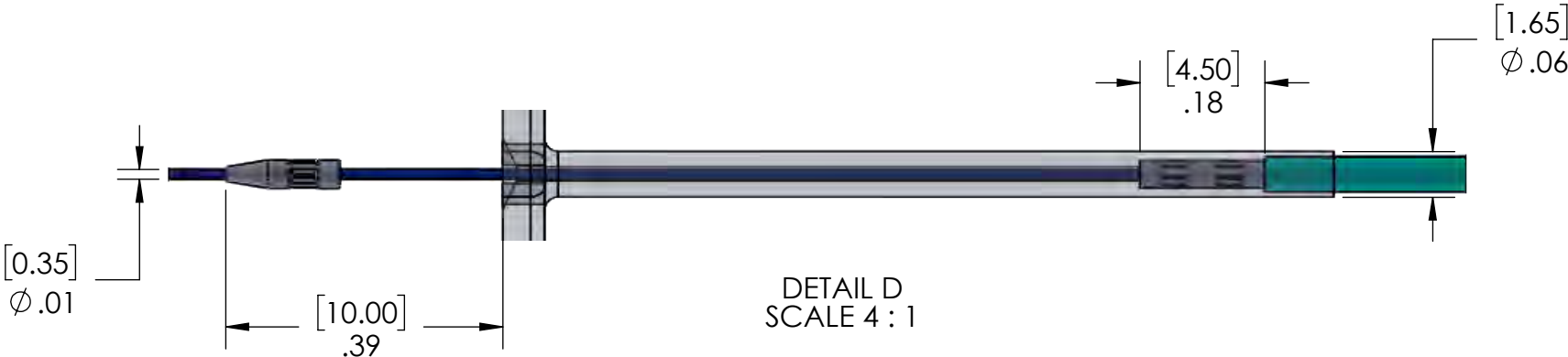
DRAFT

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D

DETAIL A
SCALE 4 : 1

DETAIL D
SCALE 4 : 1



Distal End

UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004		TITLE: EMG Lead	
DO NOT SCALE DRAWING			
PROPRIETARY AND CONFIDENTIAL			
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SIZE B	DWG. NO. 3021
		SCALE: 5:1	REV 0.1
		SHEET 3 OF 5	

Next Assembly

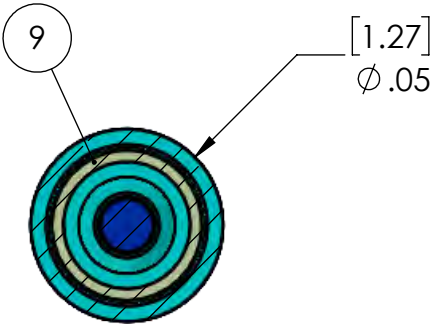
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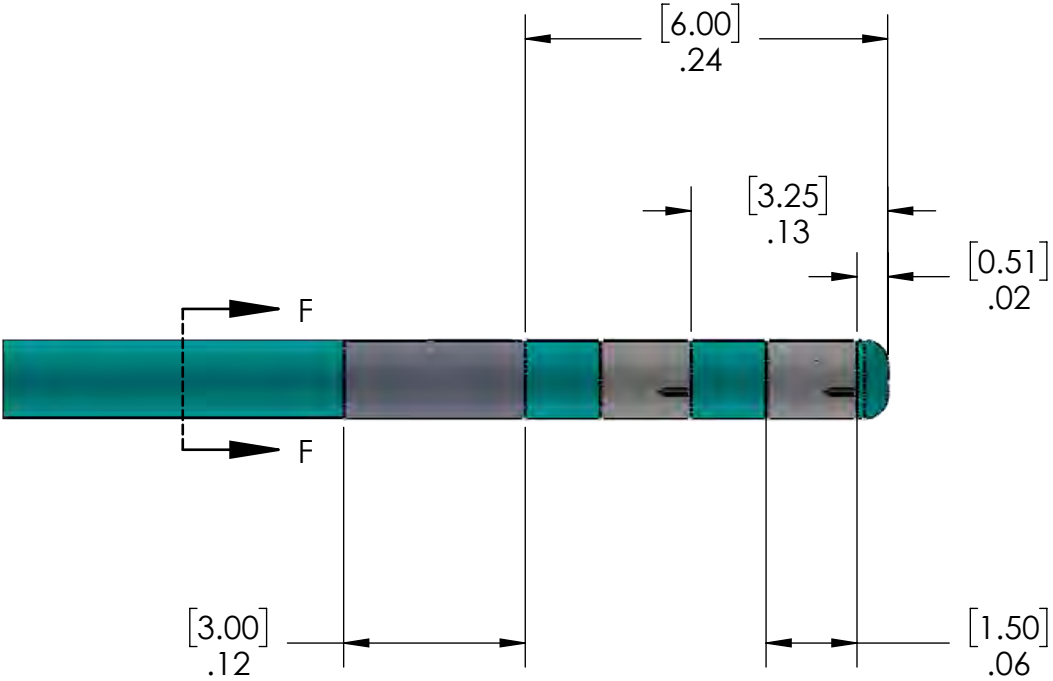
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DRAFT



SECTION F-F
SCALE 20 : 1



Proximal End

Next Assembly

UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE: EMG Lead	
PROPRIETARY AND CONFIDENTIAL		SIZE B	DWG. NO. 3021
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		REV 0.1	
		SCALE: 5:1	SHEET 4 OF 5

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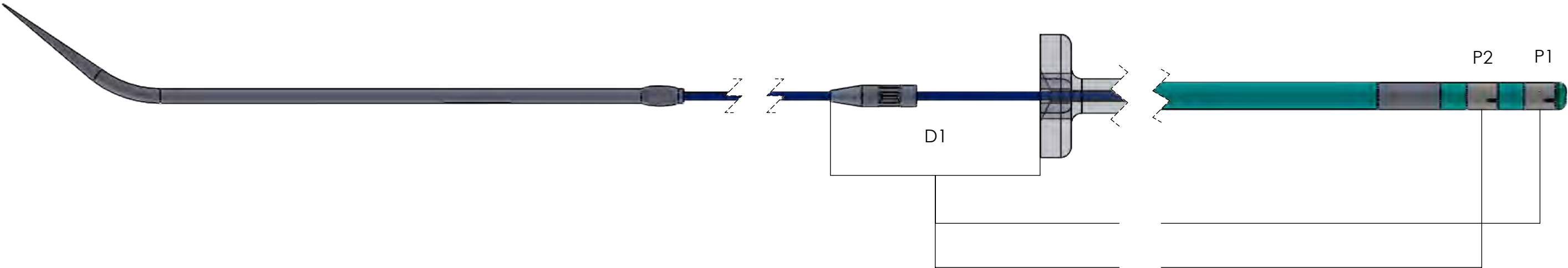
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DRAFT



UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004		TITLE: EMG Lead	
DO NOT SCALE DRAWING			
PROPRIETARY AND CONFIDENTIAL		SIZE	DWG. NO.
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		B	3021
		SCALE: 5:1	REV 0.1
		SHEET 5 OF 5	

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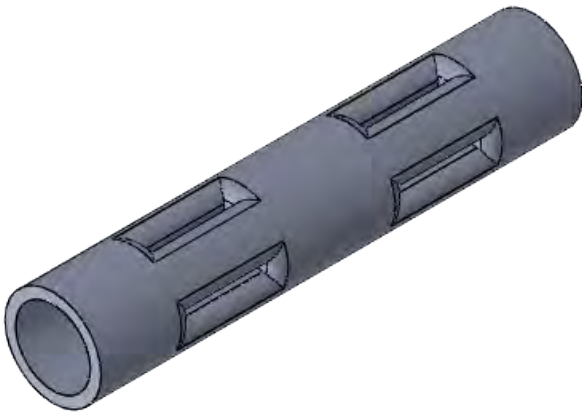
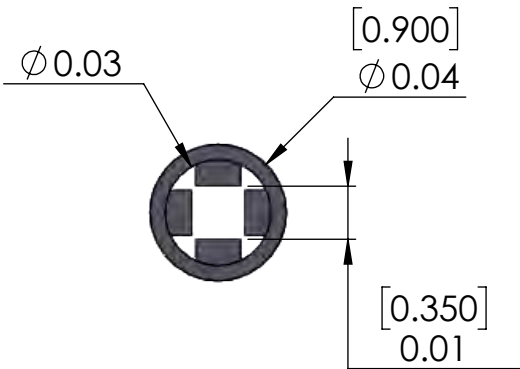
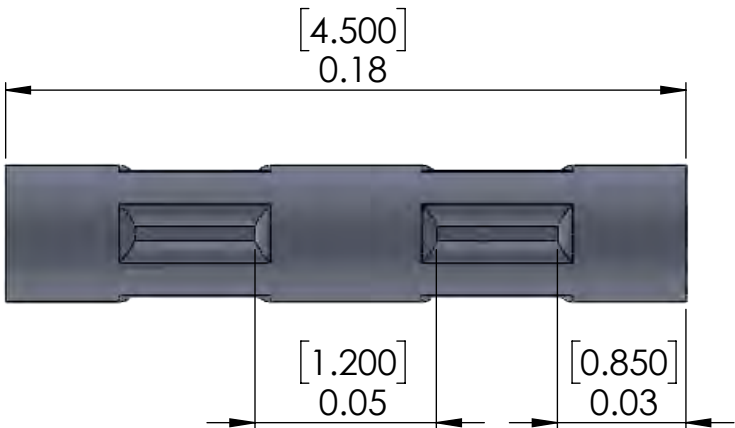
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REVISIONS				
REV.	ECO	DESCRIPTION	DRAWN BY	DATE
0.1		INITIAL RELEASE	F. ROBERTS	1 JUN 2023

DRAFT



UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL \pm ANGULAR: MACH $\pm .5$ BEND \pm TWO PLACE DECIMAL $\pm [0.20] / .008$ THREE PLACE DECIMAL $\pm [0.100] / .004$ DO NOT SCALE DRAWING		TITLE: EMG Trumpet - Crimp		
		SIZE	DWG. NO.	REV
		B	6180	0.1
		SCALE: 5:1		SHEET 1 OF 1


Next Assembly
3021

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	Drawing No:	7065	Revision:	1.0
	Part No:	7065	Created By:	J. Getsinger
	Part Description 1:	Loctite M-11FL		
	Part Description 2:	Urethane Adhesive		
Med-Ally,LLC 2040 Bushy Park Road, North Bldg 6 Goose Creek, SC 29445	Supplier Part No:	235029		
	Supplier Name:	R.S. Hughes/Henkel		
	Specification Control Drawing			

Rev	ECO Number	Description	Date
1.0	ECO 22-28	Initial Release	4Nov22



Technical Information

Agency Approvals / Certificates / Specifications	ISO 10993
Cure Type	Room Temperature (Ambient) Cure
Key Characteristics	Flexible: Highly Flexible, Peel Strength: High, Peel Strength: Viscosity: Low Viscosity
Number of Components	2 Part
Physical Form	Liquid
Shear Strength, Aluminum (etched)	1850.0 psi
Shear Strength, Steel (grit blasted)	160.0 psi
Substrates	Glass, Metal, Plastic
Mixed	
Color, Mixed	Clear; Ultra Clear
Resin	
Color, Resin	Clear
Hardener	
Color, Hardener	Clear

	Drawing No:	7073	Revision:	1.0
	Part No:	7073	Created By:	G. Early
	Part Description 1:	Silicone Adhesive, MED-2000		
	Part Description 2:	NuSil MED-2000		
Med-Ally,LLC 2040 Bushy Park Road, North Bldg 6 Goose Creek, SC 29445	Supplier Part No:	MED-2000 (Self-Leveling)		
	Supplier Name:	NuSil		
	Specification Control Drawing			

Rev	ECO Number	Description	Date
1.0	22-31	Initial Release	22Nov2022

Description

- One-part, solvent-free silicone
- Cures at room temperature upon exposure to atmospheric moisture

Applications

- Well suited for use as an adhesive for bonding and sealing silicone materials
- For applications requiring the bonding of silicone to metals, urethanes and various other substrates

NuSil Technology's MED-2000 may be considered for use in human implantation for a period of greater than 29 days.



MED-2000

Silicone adhesive

DESCRIPTION

- One part, solvent-free silicone
- Cures at room temperature upon exposure to atmospheric moisture

APPLICATION

- Well suited for use as an adhesive for bonding and sealing silicone materials
- For applications requiring the bonding of silicone to metals, urethanes and various other substrates

NuSil™ MED-2000 may be considered for use in human implantation for a period of greater than 29 days.

PROPERTIES

Typical Properties	Average Result	Standard	NT-TM
Uncured:			
Appearance	Translucent	ASTM D2090	002
Extrusion Rate**	2.5 g/minute	ASTM C603	033
Tack-Free Time	12 minutes	ASTM C679	005
Cured: 72 hours minimum at ambient temperature and humidity			
Specific Gravity	1.08	ASTM D792	003
Durometer, Type A	25	ASTM D2240	006
Tensile Strength	1,375 psi (9.5 MPa)	ASTM D412	007
Elongation	800%	ASTM D412	007
Tear Strength	80 ppi (14.1 kN/m)	ASTM D624	009
Stress at 200% Strain	110 psi (0.76 MPa)	ASTM D412	007
Tissue Culture (Cytotoxicity Testing)	Pass	USP <87> ISO 10993-5	061

The above properties are tested on a lot-to-lot basis. Do not use as a basis for preparing specifications. Please [contact](#) NuSil Technology for assistance and recommendations in establishing particular specifications.

** Performed using a Semco model 250-A pneumatic gun with a 14 gauge nozzle orifice and 90 +/- 5 psi air pressure.

INSTRUCTIONS FOR USE

Apply MED-2000, supplied in cartridges, with the use of appropriate dispensing equipment. Do not store alcohol near the worksite as traces of alcohol inhibit the catalytic system of the adhesive.

Surface Preparation

Thoroughly clean surfaces being bonded or built-up with silicone adhesive using a non-oily cleaner or mild soap to remove any surface contaminants. Do not use synthetic detergents or oil-based soaps, as they may be absorbed and subsequently leach out. Rinse first with hot water, followed by a thorough rinse using distilled water. Use compatible degreasers to clean metal surfaces.

Bonding Applications

Spread a layer of silicone adhesive on one of the surfaces. Squeeze both surfaces together to bond. Apply sufficient pressure to ensure full contact without forcing the silicone adhesive from between the pieces.

Note: Some bonding applications may require the use of a primer. NuSil Technology's MED-160 is recommended. For more information on primer selection, visit www.nusil.com and review [Choosing a Silicone Primer/Adhesive System](#).

Curing Time

Curing or vulcanization time depends upon the thickness of the silicone adhesive layer, relative humidity, and accessibility of atmospheric moisture to the curing adhesive. For sections of typical thickness, a relative humidity level between 20-60% is recommended to cure the adhesive at room temperature.

Generally the adhesive forms a thick, tack-free outer skin for thick section films within a few minutes after application. The vulcanization rate slows when exposing very thin films to excessive humidity (80% relative air humidity). For films below 80 microns, the relative air humidity should be within 30% - 50%.

Because MED-2000 cures upon exposure to atmospheric moisture, keep tubes tightly closed when not in use. A plug of cured material may form in the tip of the tube. Remove or dispense the plug from the tube before using.

Non-Sterile Packaged Units

The acidic nature of MED-2000 provides a natural bactericidal effect. While containers may be relatively free of microorganisms, they can not be considered sterile unless subjected to a validated sterilization process. When the adhesive is fully cured it can withstand sterilization with ethylene oxide, dry heat, or steam autoclaving. The size and shape of fabricated articles must be considered when

Packaging

8 Gram Tube
2 Ounce Tube (59 mL)
5 Ounce Tube (148 mL)
6 Ounce Semco® Tube
12 Ounce Semco® Tube

Warranty

12 Months

establishing the conditions of sterilization. Larger quantities and larger parts may require longer periods of heating and may retain ethylene oxide longer than small parts. It is the user's responsibility to determine the out-gassing time required for a particular application if ethylene oxide sterilization methods are used.

Caution

Do not use MED-2000 in its uncured state to repair or encapsulate living tissue in the body. During curing, approximately 4-5% acetic acid (vinegar-like odor) is generated in vapor form. Avoid contact with eyes and skin, as uncured adhesive irritates. Take appropriate precautions if wearing contact lenses. In case of contact, flush eyes with water, use a dry towel to remove from skin and contact a physician. Keep out of REACH of children.

FDA MASTER FILE

A Master File for MED-2000 has been filed with the U.S. Food and Drug Administration. Customers interested in authorization to reference the Master File must [contact](#) NuSil Technology.

REACH COMPLIANCE

Please [contact](#) NuSil Technology's Regulatory Compliance department with any questions or for further assistance.

SPECIFICATIONS

Do not use the properties shown in this technical profile as a basis for preparing specifications. Please [contact](#) NuSil Technology for assistance and recommendations in establishing particular specifications.

WARRANTY INFORMATION

The warranty period provided by NuSil Technology LLC (hereinafter "NuSil Technology") is 12 months from the date of shipment when stored below 40°C in original unopened containers. Unless NuSil Technology provides a specific written warranty of fitness for a particular use, NuSil Technology's sole warranty is that the product will meet NuSil Technology's then current specification. NuSil Technology specifically disclaims all other expressed or implied warranties, including, but not limited to, warranties of merchantability and fitness for use. The exclusive remedy and NuSil Technology's sole liability for breach of warranty is limited to refund of purchase price or replacement of any product shown to be other than as warranted. NuSil Technology expressly disclaims any liability for incidental or consequential damages.

WARNINGS ABOUT PRODUCT SAFETY

NuSil Technology believes, to the best of its knowledge, that the information and data contained herein are accurate and reliable. The user is responsible to determine the material's suitability and safety of use. NuSil Technology cannot know each application's specific requirements and hereby notifies the user that it has not tested or determined this material's suitability or safety for use in any application. The user is responsible to adequately test and determine the safety and suitability for their application and NuSil Technology makes no warranty concerning fitness for any use or purpose. NuSil

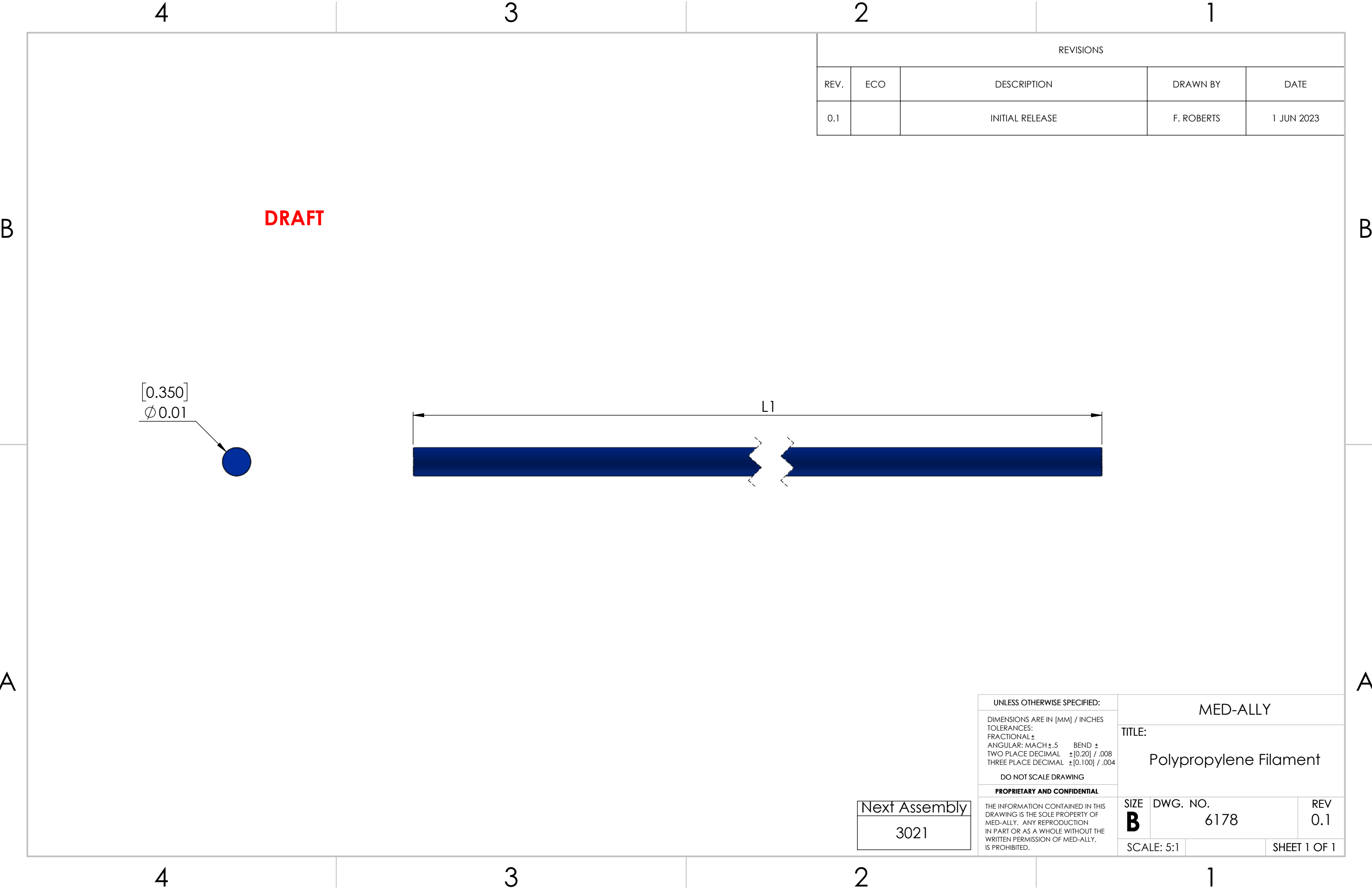
Technology has completed no testing to establish safety of use in any medical application.

NuSil Technology has tested this material only to determine if the product meets the applicable specifications. (Please [contact](#) NuSil Technology for assistance and recommendations when establishing specifications.) When considering the use of NuSil Technology products in a particular application, review the latest Material Safety Data Sheet and [contact](#) NuSil Technology with any questions about product safety information.

Do not use any chemical in a food, drug, cosmetic, or medical application or process until having determined the safety and legality of the use. The user is responsible to meet the requirements of the U.S. Food and Drug Administration (FDA) and any other regulatory agencies. Before handling any other materials mentioned in the text, the user is advised to obtain available product safety information and take the necessary steps to ensure safety of use.

PATENT / INTELLECTUAL PROPERTY WARNING

NuSil Technology disclaims any expressed or implied warranty against the infringement of any domestic or international patent/intellectual property right. NuSil Technology does not warrant the use or sale of the products described herein will not infringe the claims of any domestic or international patent/intellectual property right covering the product itself, its use in combination with other products, or its use in the operation of any process.



REVISIONS				
REV.	ECO	DESCRIPTION	DRAWN BY	DATE
0.1		INITIAL RELEASE	F. ROBERTS	1 JUN 2023

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE: Polypropylene Filament		
		SIZE	DWG. NO.	REV
		B	6178	0.1
		SCALE: 5:1		SHEET 1 OF 1

Next Assembly
3021

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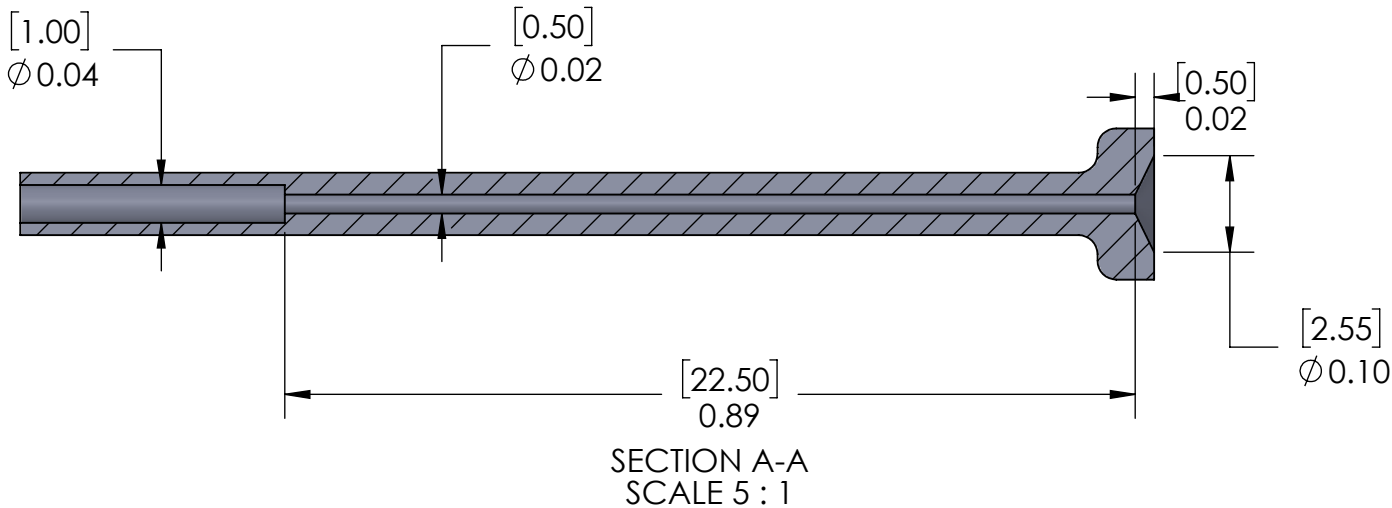
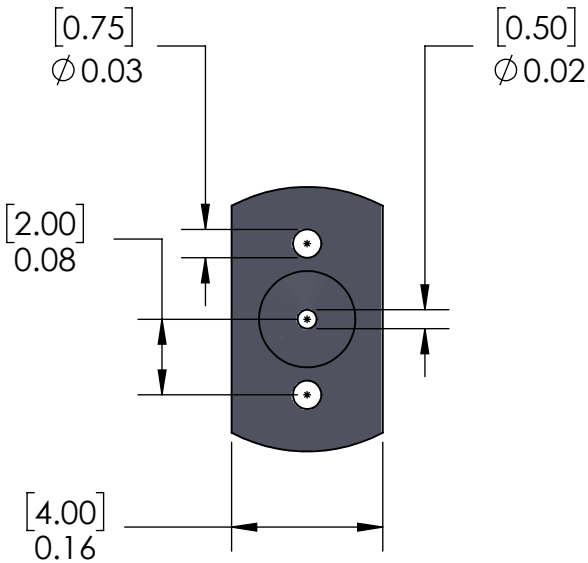
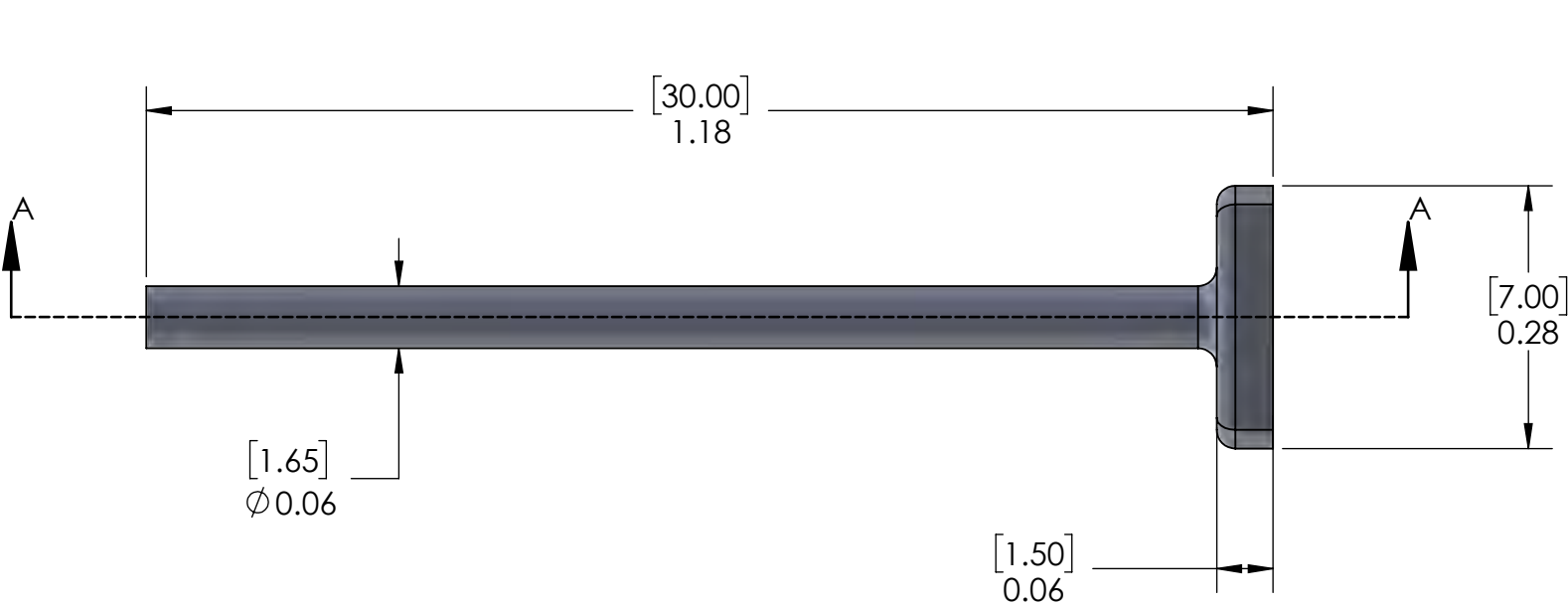
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REVISIONS

REV.	ECO	DESCRIPTION	DRAWN BY	DATE
0.1		INITIAL RELEASE	F. Roberts	30 Mar 2023

DRAFT



Notes:
1. Material: Implant Grade Silicone

Next Assembly
3021

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING PROPRIETARY AND CONFIDENTIAL THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		TITLE: Trumpet Anchor		
		SIZE B	DWG. NO. 6179	REV 0.1
		SCALE: 5:1		SHEET 1 OF 1

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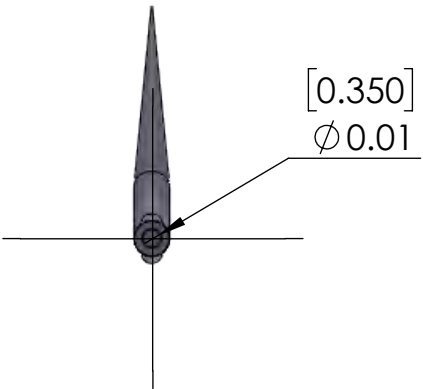
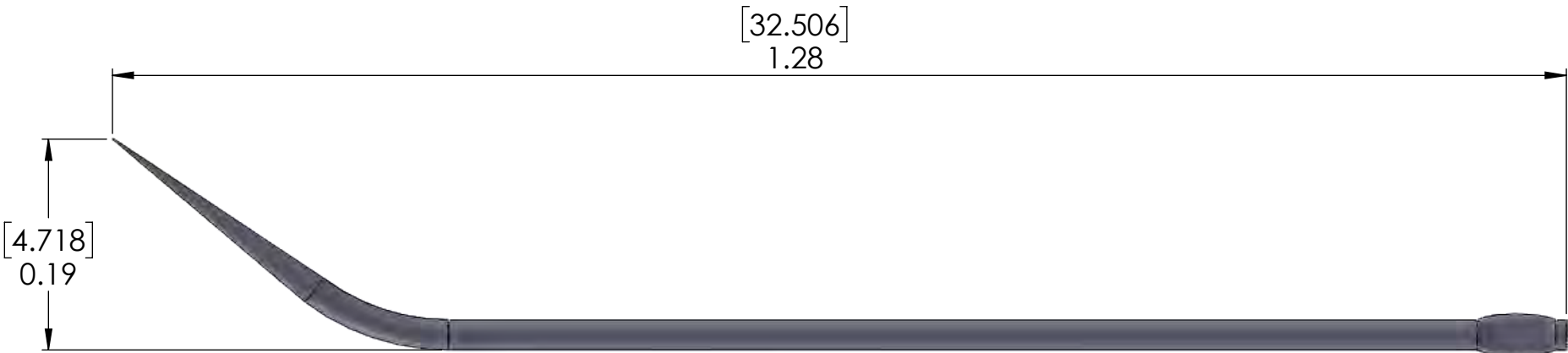
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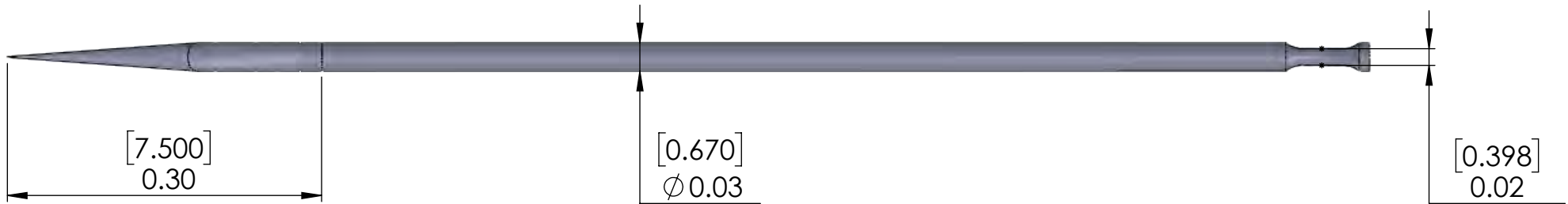
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REVISIONS				
REV.	ECO	DESCRIPTION	DRAWN BY	DATE
0.1		INITIAL RELEASE	F. ROBERTS	30 MAR 2023

B



A



B

A

Notes:
1. Material: 316L Stainless Steel

Next Assembly
3021

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE: EMG Suture-Needle		
		SIZE B	DWG. NO. 7085	REV 0.1
		SCALE: 5:1		SHEET 1 OF 1
		THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		

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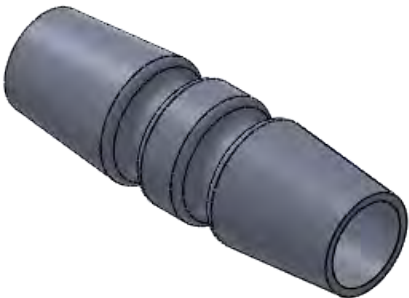
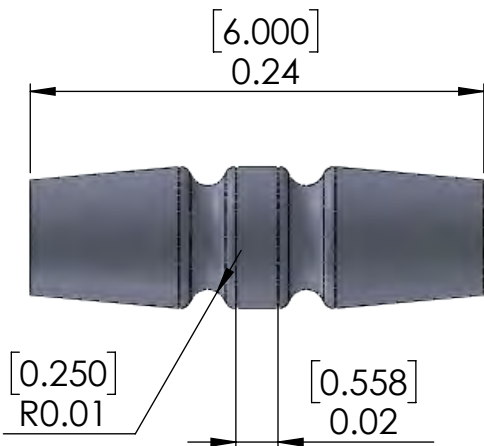
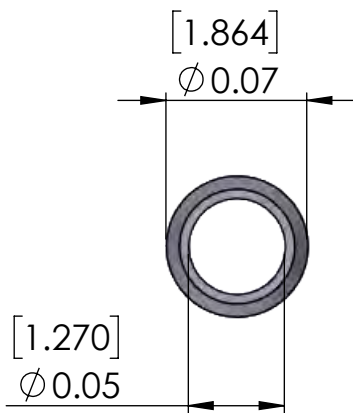
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REVISIONS				
REV.	ECO	DESCRIPTION	DRAWN BY	DATE
0.1		INITIAL RELEASE	F.ROBERTS	24 MAR 2023

DRAFT



- Notes:
- 1. Model Number: 8276
 - 2. Material: Implant Grade Silicone

Next Assembly
3020

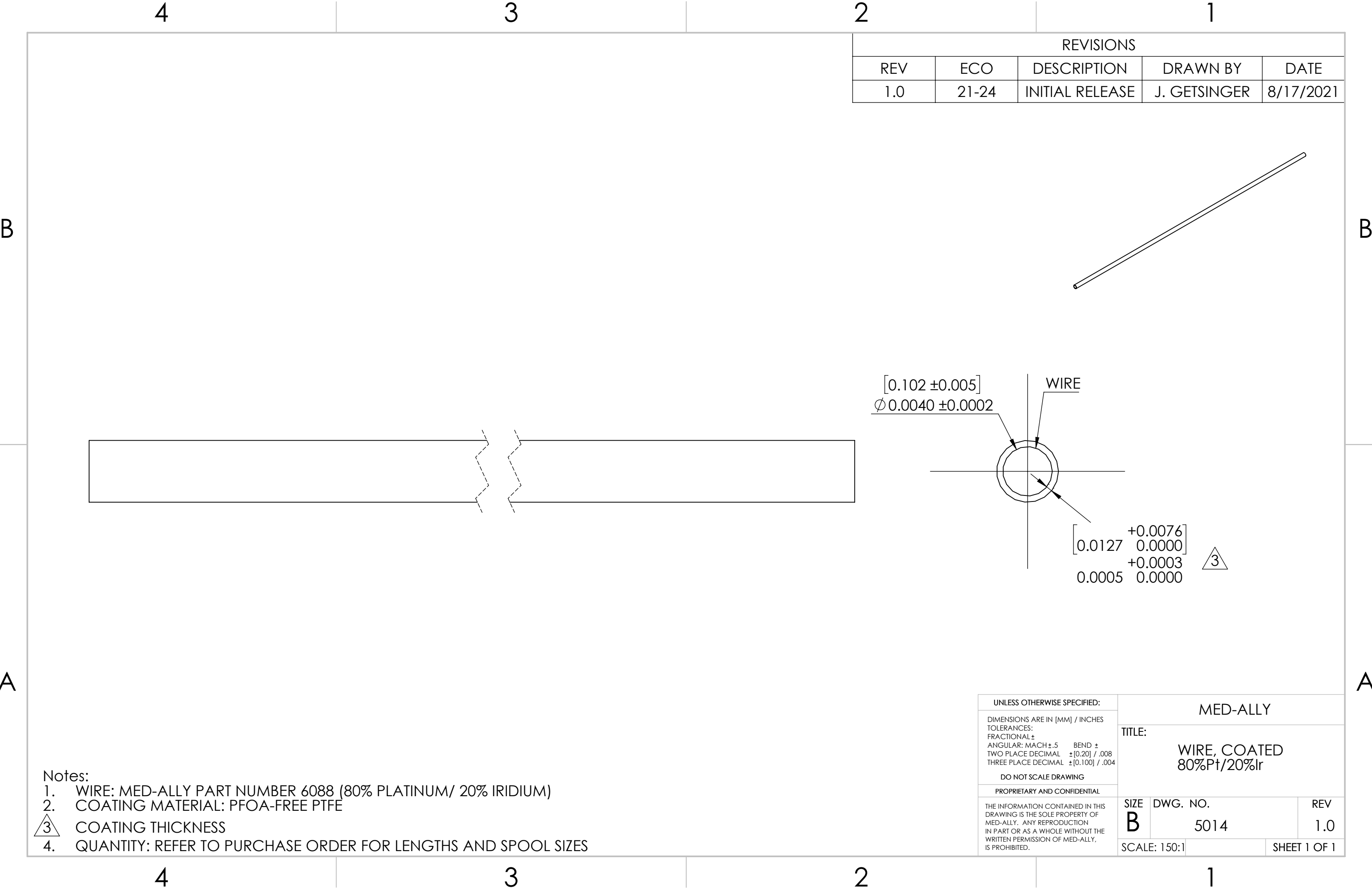
UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE: Suture Sleeve		
		SIZE	DWG. NO.	REV
		B	6176	0.1
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SCALE: 5:1		SHEET 1 OF 1

4

3

2

1



REVISIONS				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	21-24	INITIAL RELEASE	J. GETSINGER	8/17/2021

- Notes:
1. WIRE: MED-ALLY PART NUMBER 6088 (80% PLATINUM/ 20% IRIIDIUM)
 2. COATING MATERIAL: PFOA-FREE PTFE
 - $\triangle 3$ 3. COATING THICKNESS
 4. QUANTITY: REFER TO PURCHASE ORDER FOR LENGTHS AND SPOOL SIZES

UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL \pm ANGULAR: MACH $\pm .5$ BEND \pm TWO PLACE DECIMAL $\pm [0.20] / .008$ THREE PLACE DECIMAL $\pm [0.100] / .004$ DO NOT SCALE DRAWING		TITLE: WIRE, COATED 80%Pt/20%Ir	
PROPRIETARY AND CONFIDENTIAL		SIZE B	REV 1.0
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SCALE: 150:1	SHEET 1 OF 1

4

3

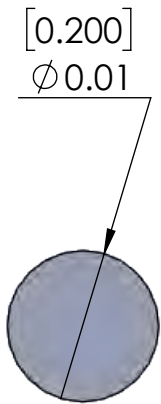
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1

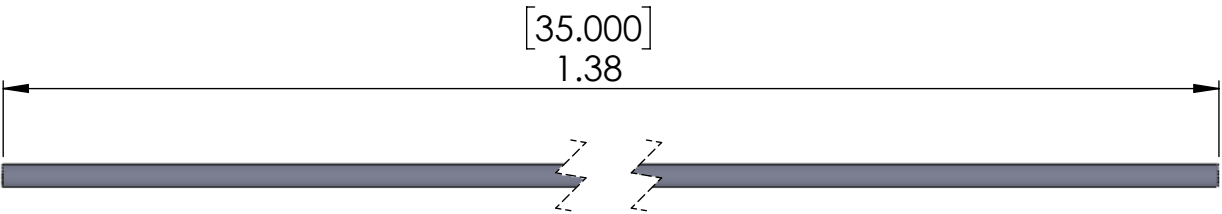
REVISIONS

REV.	ECO	DESCRIPTION	DRAWN BY	DATE
0.1		INITIAL RELEASE	F. ROBERTS	2 JUN 2023

DRAFT



Scale: 100:1



Notes:
1. Material: Silk Braided Suture

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE: Suture - 35mm		
PROPRIETARY AND CONFIDENTIAL		SIZE	DWG. NO.	REV
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		B	6170	0.1
		SCALE: 5:1		SHEET 1 OF 1

Next Assembly
3018

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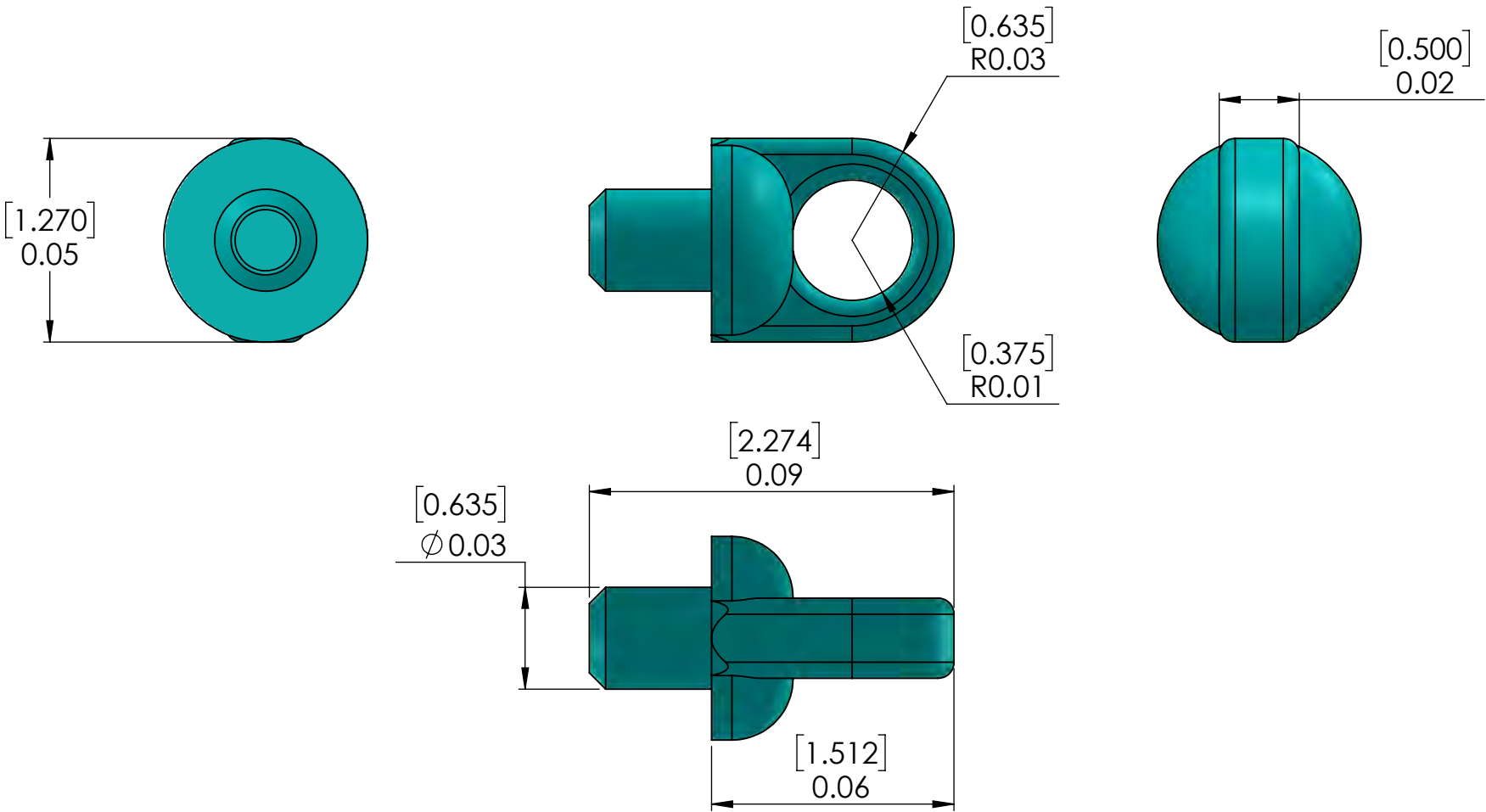
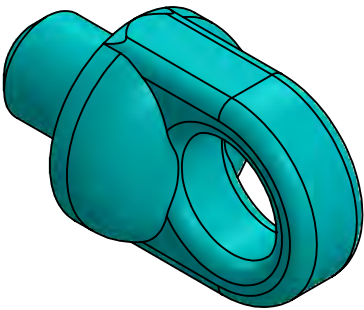
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REVISIONS

REV.	ECO	DESCRIPTION	DRAWN BY	DATE
0.1			F. ROBERTS	24 MAR 2023

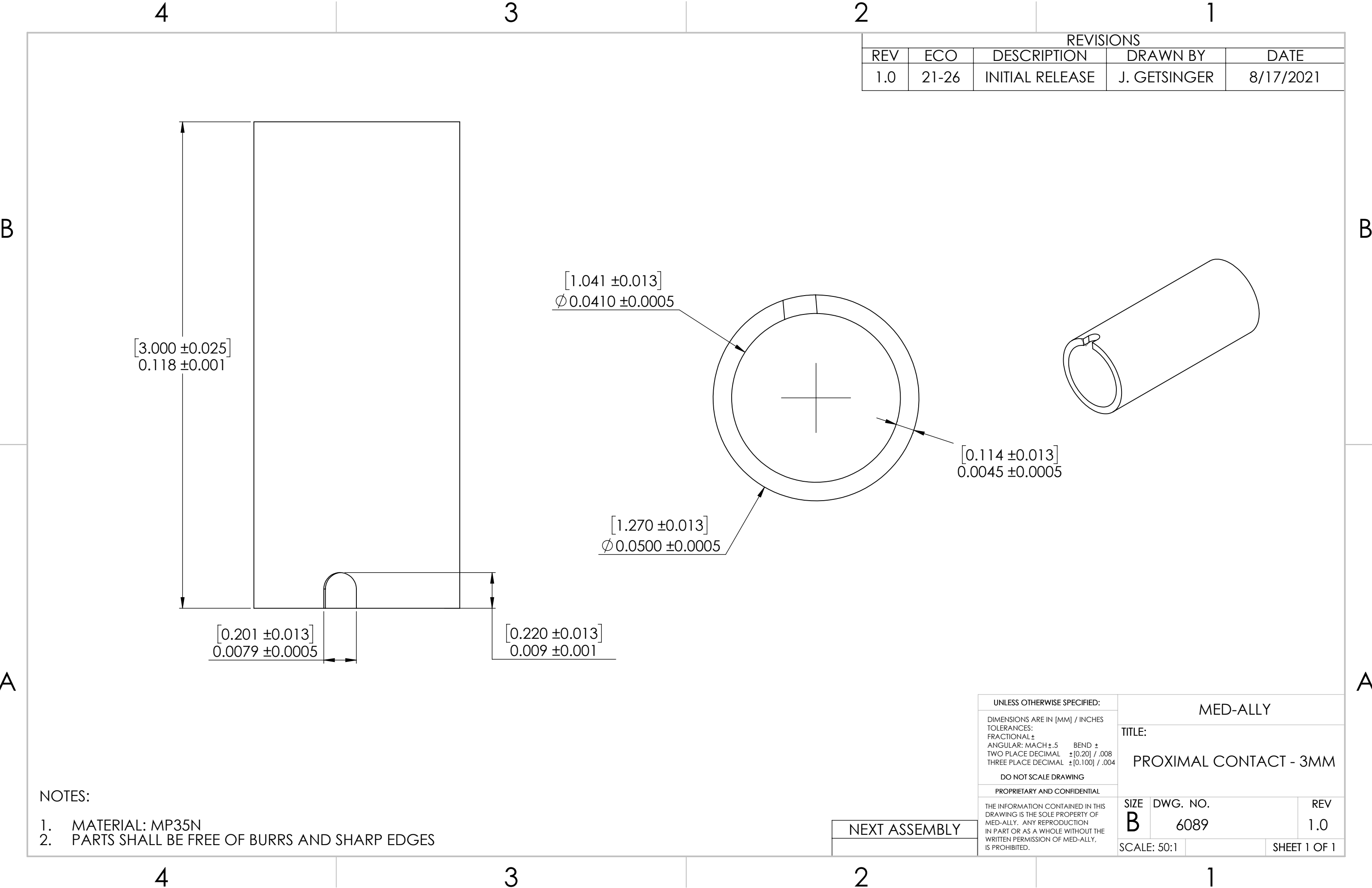
DRAFT



- Notes:
- Model Number: 8275
 - Material: Epoxy EPO-TEK 301

Next Assembly
3020

UNLESS OTHERWISE SPECIFIED:					MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING PROPRIETARY AND CONFIDENTIAL THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.					TITLE: Distal Suture Tip	
					SIZE B	REV 0.1
					DWG. NO. 6175	
SCALE: 5:1			SHEET 1 OF 1			



REVISIONS				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	21-26	INITIAL RELEASE	J. GETSINGER	8/17/2021

- NOTES:
- MATERIAL: MP35N
 - PARTS SHALL BE FREE OF BURRS AND SHARP EDGES

NEXT ASSEMBLY

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE:		
		PROXIMAL CONTACT - 3MM		
		SIZE	DWG. NO.	REV
		B	6089	1.0
PROPRIETARY AND CONFIDENTIAL		SCALE: 50:1		
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SHEET 1 OF 1		

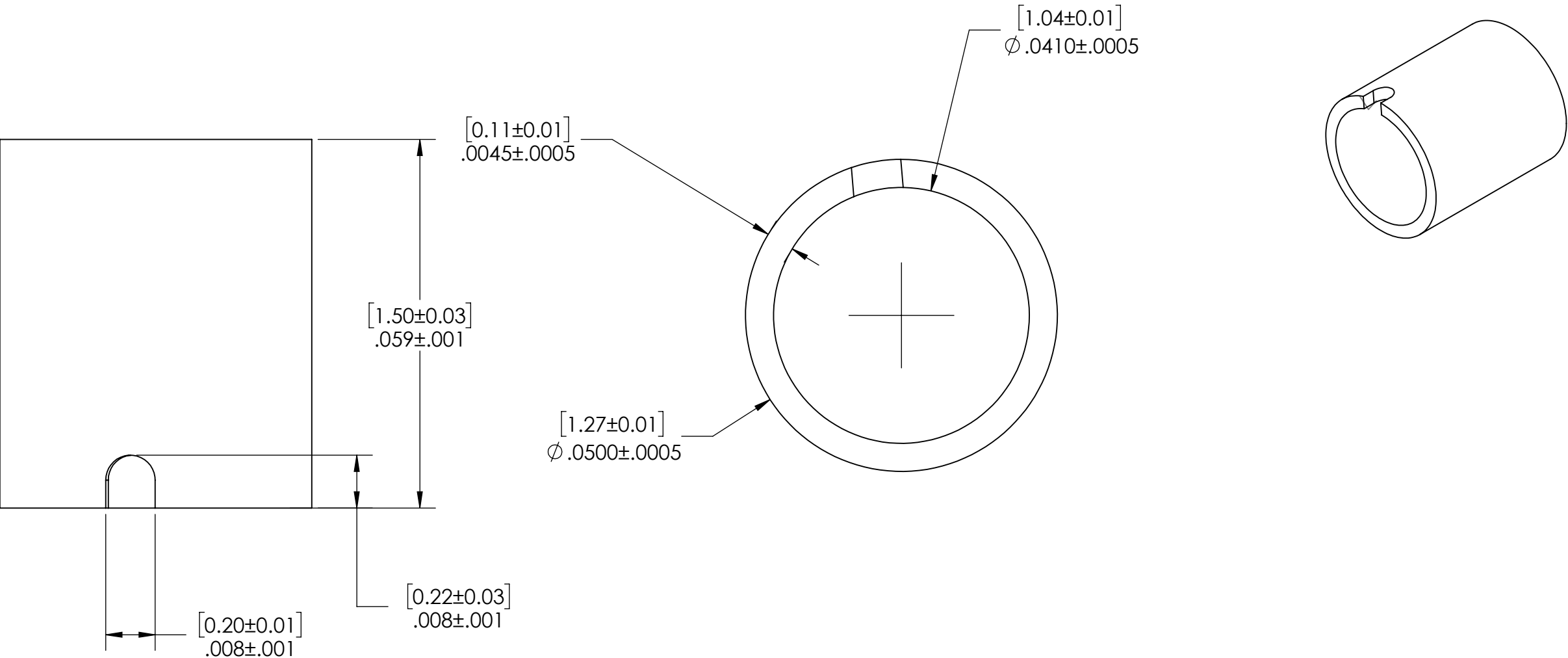
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REVISIONS				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	21-26	INITIAL RELEASE	J. GETSINGER	8/17/2021
2.0	21-37	RE-RELEASE	J. GETSINGER	10/13/2021



NOTES:

1. MATERIAL: MP35N
2. PARTS SHALL BE FREE OF BURRS AND SHARP EDGES

NEXT ASSEMBLY

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE: PROXIMAL CONTACT - 1.5MM		
		PROPRIETARY AND CONFIDENTIAL		
		THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		
		SIZE B	DWG. NO. 6090	REV 2.0
SCALE: 50:1		SHEET 1 OF 1		

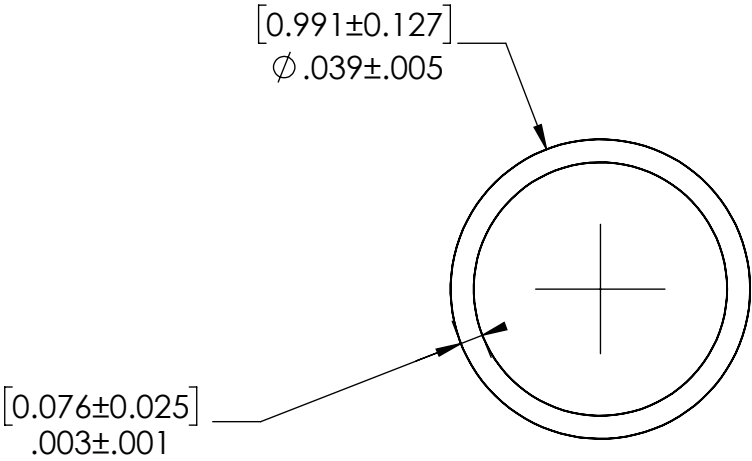
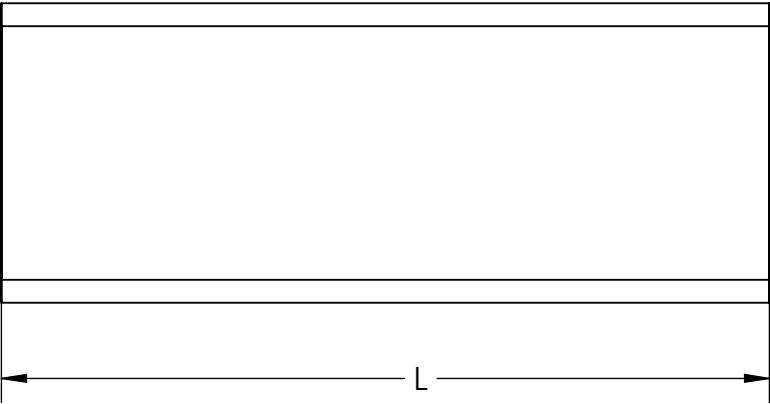
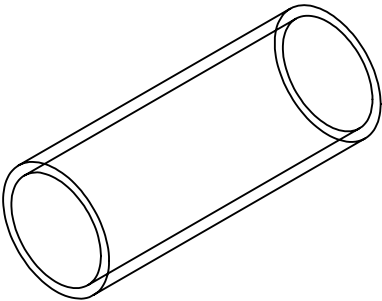
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Revisions				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	22-28	INITIAL RELEASE	J. GETSINGER	4NOV22



- NOTES:
1. MATERIAL: PEEK
 2. LENGTH (L) WILL BE DISTINGUISHED ON PO

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE:		
		PEEK SINGLE LUMEN TUBE		
		SIZE	DWG. NO.	REV
		B	6153	1.0
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SCALE: 40:1		SHEET 1 OF 1

4

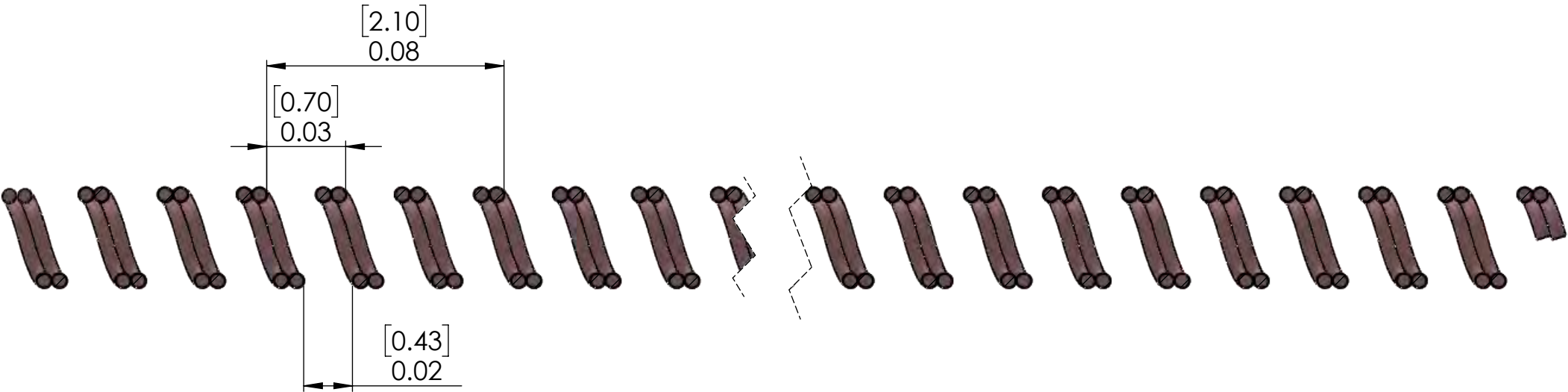
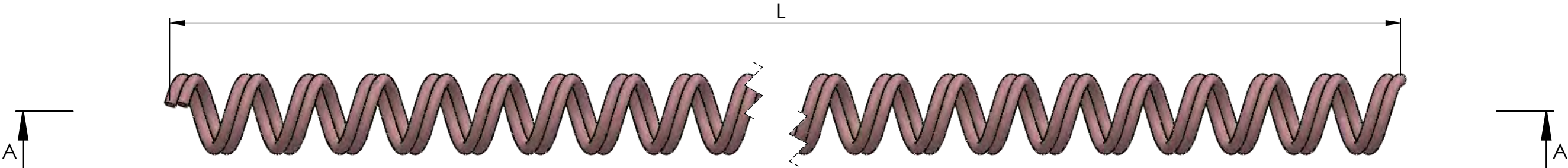
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DRAFT

REVISIONS				
REV.	ECO	DESCRIPTION	DRAWN BY	DATE
0.1		INITIAL RELEASE	F. ROBERTS	9 JUN 2023



SECTION A-A
SCALE 20 : 1

NOTES:
1. LENGTH L DEFINED IN HIGHER ASSEMBLIES

Next Assembly

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE:		
		2 Filar Coil		
		SIZE	DWG. NO.	REV
		B	5036	0.1
PROPRIETARY AND CONFIDENTIAL		SCALE: 5:1		
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SHEET 1 OF 1		

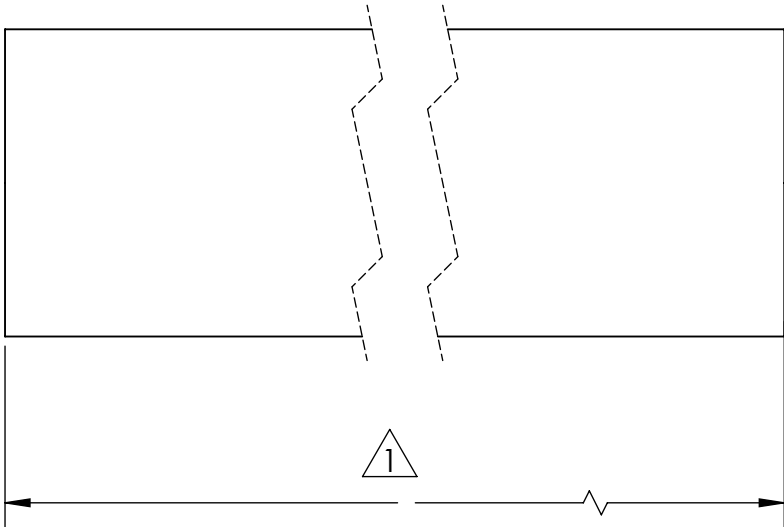
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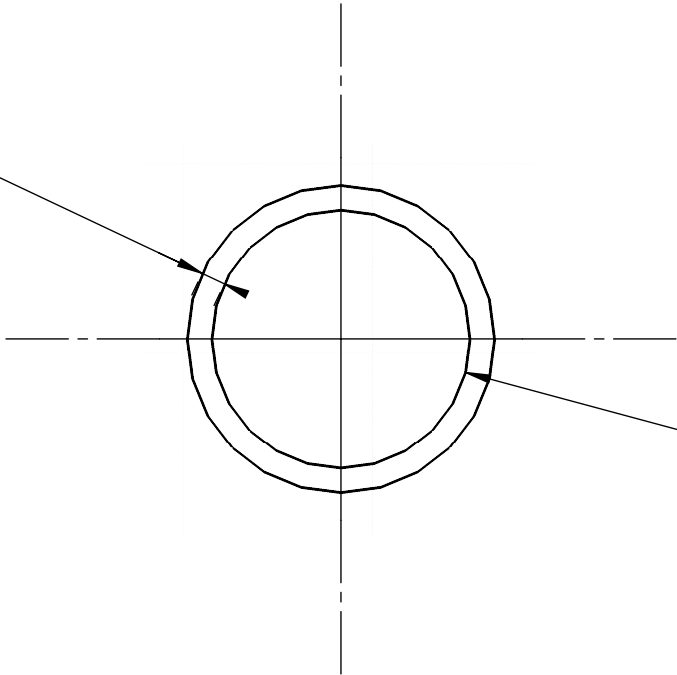
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REVISIONS				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	21-24	INITIAL RELEASE	J. GETSINGER	12AUG21
2.0	21-45	REMOVED MATERIAL FROM NAME, CHANGED ID FROM 0.039 TO 0.042 AND DIMENSIONED WALL INSTEAD OF OD	J.GETSINGER	6DEC21



[0.10±0.04]
.0040±.0015



[1.07±0.04]
Ø.0420±.0015

- NOTES:
- 1 REFER TO TUBING LENGTH SPECIFIED ON PURCHASE ORDER
 2. MATERIAL: POLYURETHANE, 55D

UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING PROPRIETARY AND CONFIDENTIAL THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		TITLE: OUTER TUBING	
		SIZE B	REV 2.0
		DWG. NO. 6085	DATE 12AUG21
		SCALE: 32:1	SHEET 1 OF 1

4

3

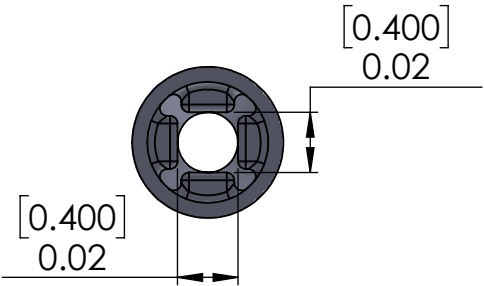
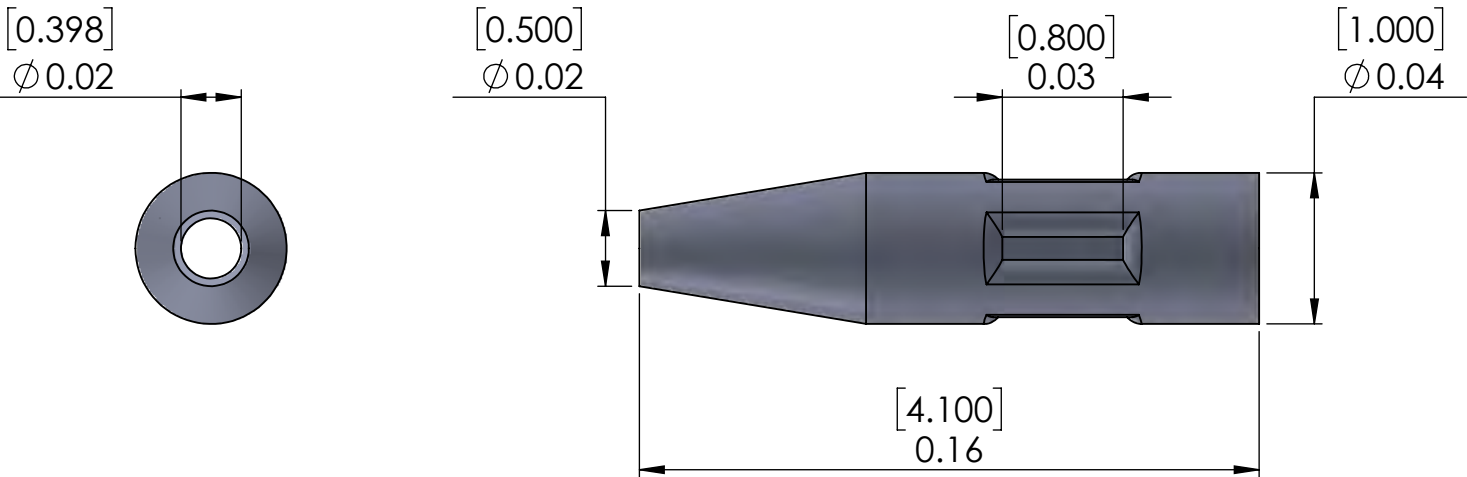
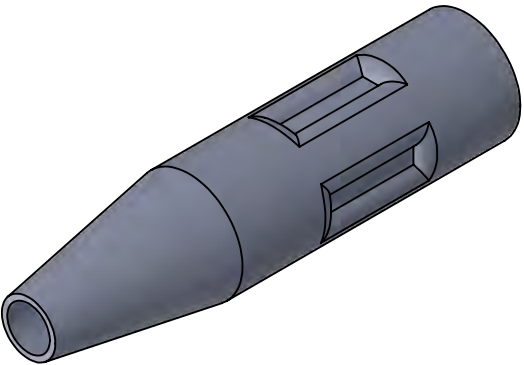
2

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REVISIONS

REV.	ECO	DESCRIPTION	DRAWN BY	DATE
0.1		INITIAL RELEASE	F. ROBERTS	30 MAR 2023

DRAFT

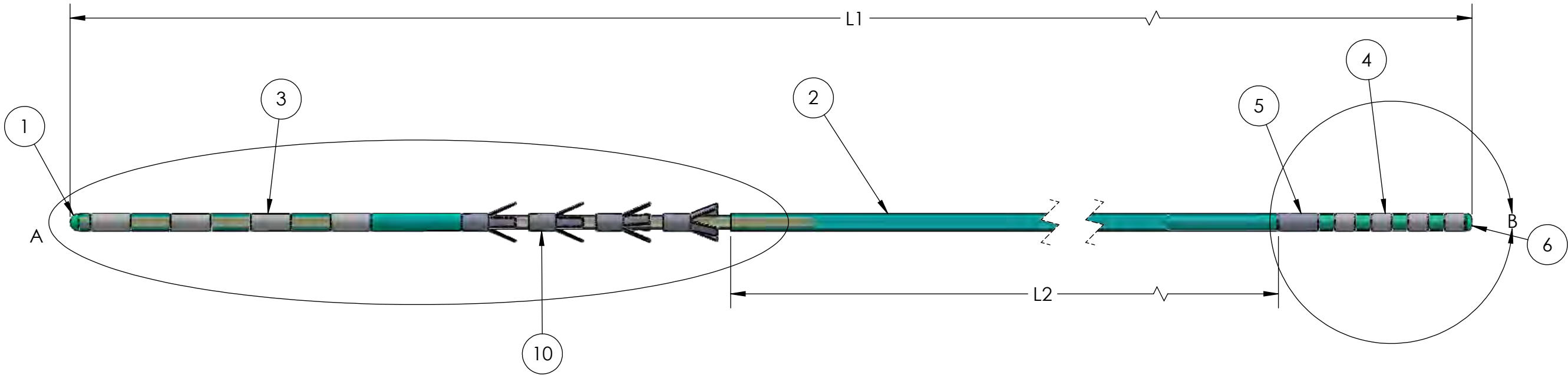


Notes:
1. Material: 316L Stainless Steel

Next Assembly
3021

UNLESS OTHERWISE SPECIFIED:				
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004				
DO NOT SCALE DRAWING				
PROPRIETARY AND CONFIDENTIAL				
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.				
TITLE:		MED-ALLY		
EMG Suture-Crimp				
SIZE	DWG. NO.	REV		
B	6177	0.1		
SCALE: 5:1		SHEET 1 OF 1		

REVISIONS				
REV.	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	22-19	INITIAL RELEASE	J. GETSINGER	16MAY22
2.0	22-30	REMOVED MARKER BANDS, REPLACED EPOXY WITH URETHANE, UPDATED QUANTITY FOR TUBING TO ACCOUNT FOR NO SPACERS BETWEEN THE CONTACTS, ADDED PEEK INNER TUBING ON PROXIMAL END, CHANGED CONNECTIONS	J. GETSINGER	18NOV22
3.0		CORRECTED L2 LENGTHS FOR NON-TINE PARTS, CORRECTED TINE LABEL ON PAGE 1 FROM 9 TO 10, ADDED LENGTH FOR SPACE BETWEEN ELECTRODES AND TINES ON PAGE 3	J. GETSINGER	



PART NUMBER	L1 (MM)	L2 (MM)
3011-350	350	313
3011-350T	350	285
3011-500	500	463
3011-500T	500	435

ITEM NO.	PART NUMBER	DESCRIPTION	QTY
1	6083	TIP, DISTAL	1
2	6085-1	OUTER TUBING	L2
3	6081-3	ELECTRODE, 3.00 MM	4
4	6090	CONTACT, PROXIMAL, 1.50 MM	4
5	6089	CONTACT, PROXIMAL, 3.00 MM	1
6	6101	TIP, PROXIMAL	1
7	5019	4 FILAR COIL	1
8	6084-4	INNER TUBING	67 MM
9	6153	PEEK SINGLE LUMEN TUBE	25 MM
10	6222	TINE	4
11	7065	LOCTITE M-11FL URETHANE ADHESIVE	A/R

- NOTES;
UNLESS OTHERWISE SPECIFIED;
1. ASSEMBLY SHALL BE CLEAN AND FREE OF DIRT, GREASE AND OTHER PROCESS CONTAMINATES
 2. DC LEAD RESISTANCE SHALL BE LESS THAN 50 OHMS FOR EACH CONDUCTOR FROM CONTACT TO ELECTRODE
 3. ELECTRICAL CONNECTIONS: SEE SHEET 5 OF THIS DRAWING
 4. MATERIAL CERTIFICATION AND TRACIBILITY ARE REQUIRED FOR ALL PARTS
 5. OUTER AND INNER TUBING WILL BE CUT TO SIZE TO FIT ASSEMBLY
 6. THE T IN THE PART NUMBER REPRESENTS THE LEAD HAS TINES

DRAFT

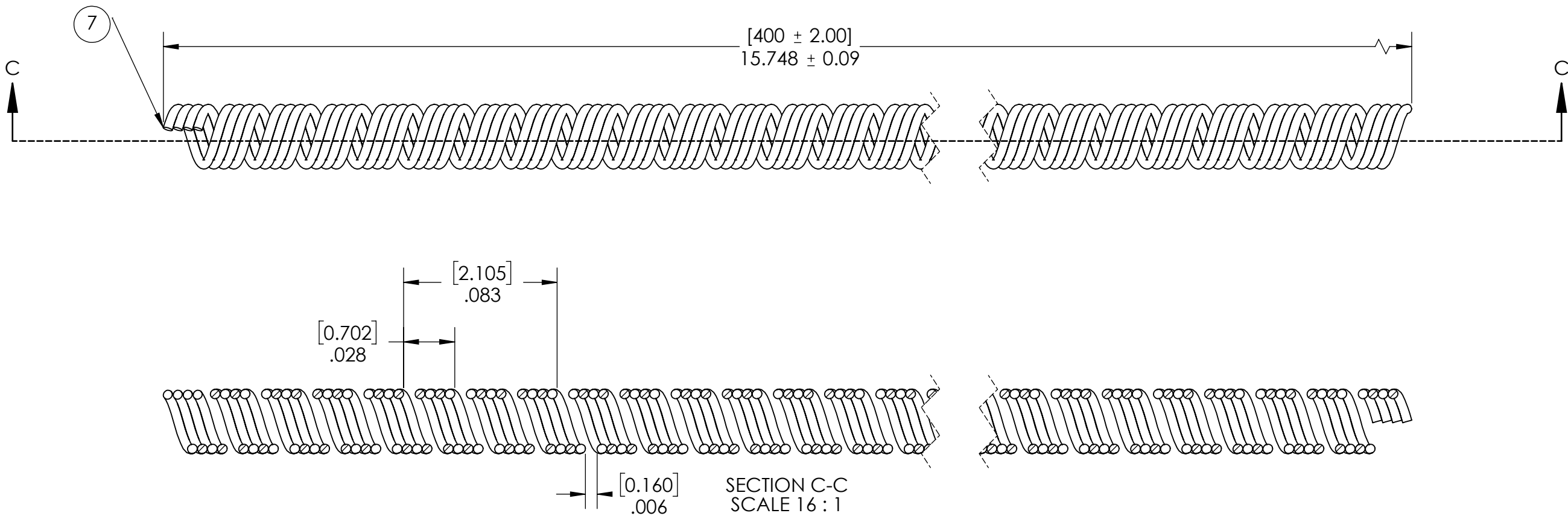
UNLESS OTHERWISE SPECIFIED:			MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING			TITLE: 4X4 LEAD - 3 MM ELECTRODES	
PROPRIETARY AND CONFIDENTIAL THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.			SIZE B	DWG. NO. 3011
			REV 3.0	
SCALE: 1:2			SHEET 1 OF 5	

B

B

A

A



DRAFT

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE:		
		4X4 LEAD - 3 MM ELECTRODES		
		SIZE	DWG. NO.	REV
		B	3011	3.0
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SCALE: 4:1		SHEET 2 OF 5

4

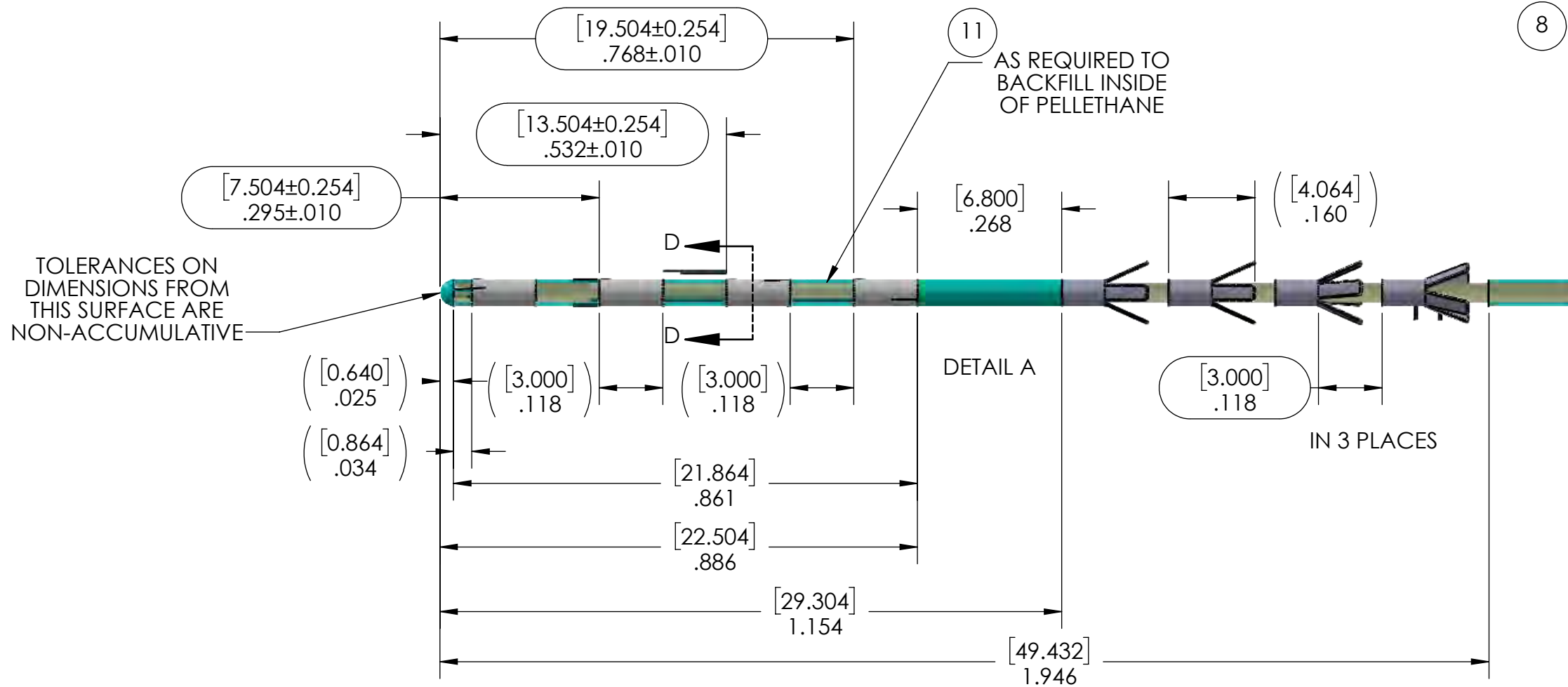
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B

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DISTAL END

DRAFT

UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES		TITLE:	
TOLERANCES:		4X4 LEAD - 3 MM ELECTRODES	
FRACTIONAL ±		SIZE	DWG. NO.
ANGULAR: MACH ±.5 BEND ±		B	3011
TWO PLACE DECIMAL ±[0.20] / .008		SCALE: 4:1	REV
THREE PLACE DECIMAL ±[0.100] / .004			3.0
DO NOT SCALE DRAWING		SHEET 3 OF 5	
PROPRIETARY AND CONFIDENTIAL			
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.			

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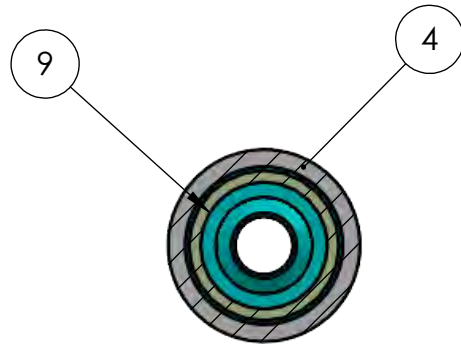
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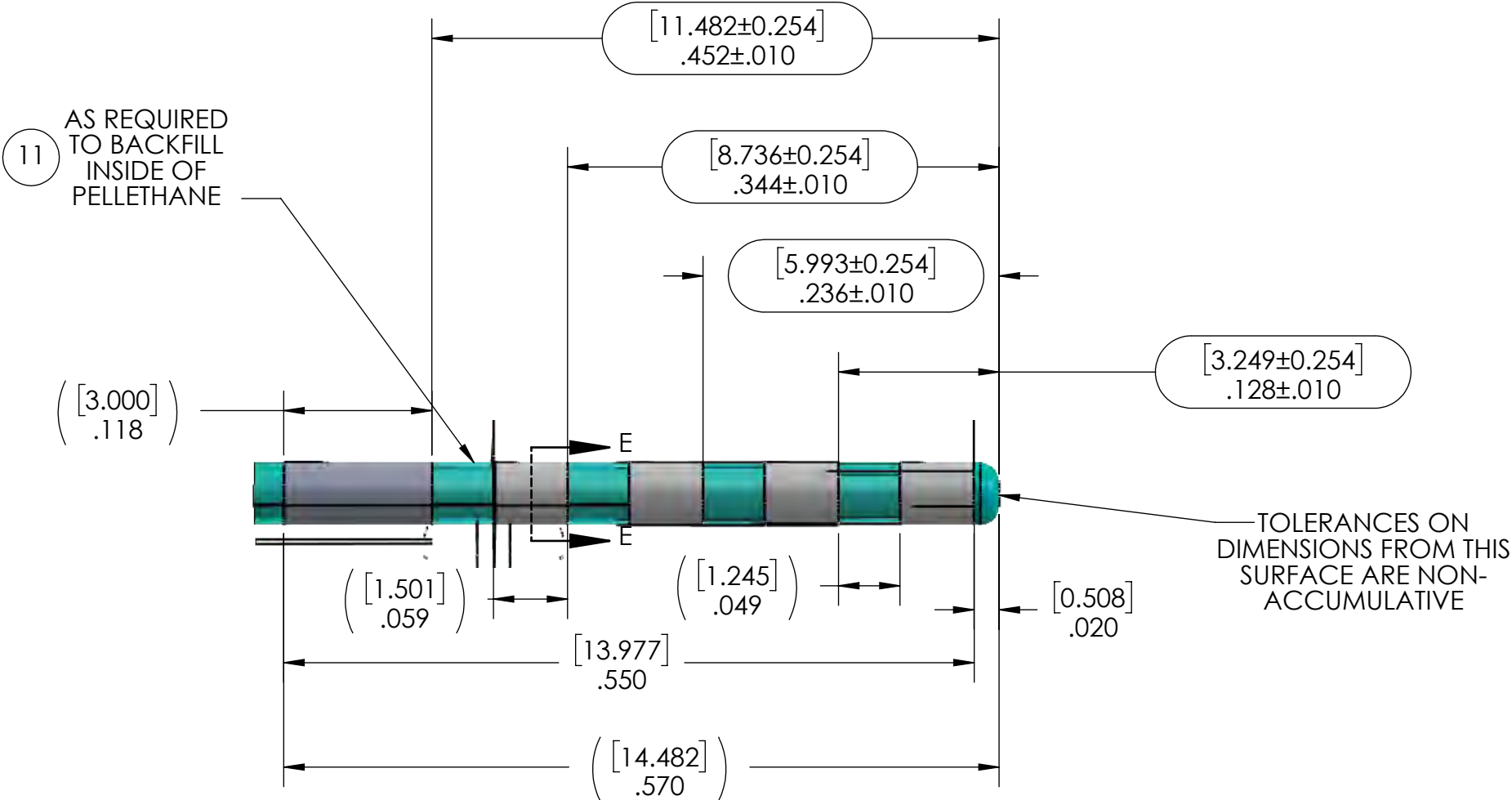
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SECTION E-E
SCALE 20 : 1



DETAIL B
SCALE 8 : 1

DRAFT

PROXIMAL END

UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE: 4X4 LEAD - 3 MM ELECTRODES	
PROPRIETARY AND CONFIDENTIAL		SIZE B	REV 3.0
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		DWG. NO. 3011	SHEET 4 OF 5

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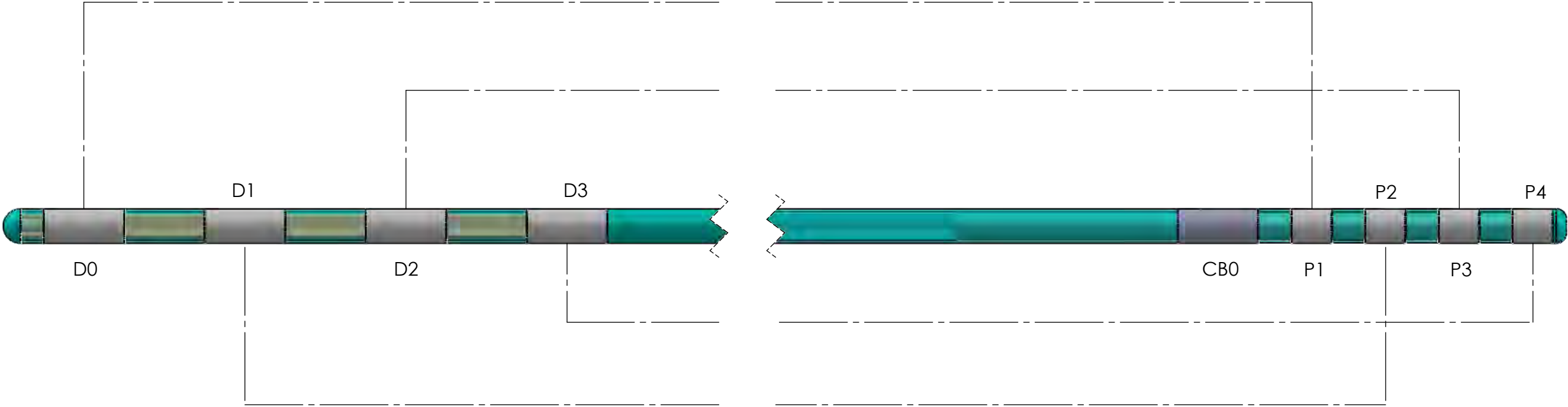
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B

B

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DRAFT

UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE: 4X4 LEAD - 3 MM ELECTRODES	
		PROPRIETARY AND CONFIDENTIAL	
		THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.	
SIZE B	DWG. NO. 3011	REV 3.0	
SCALE: 1:2		SHEET 5 OF 5	

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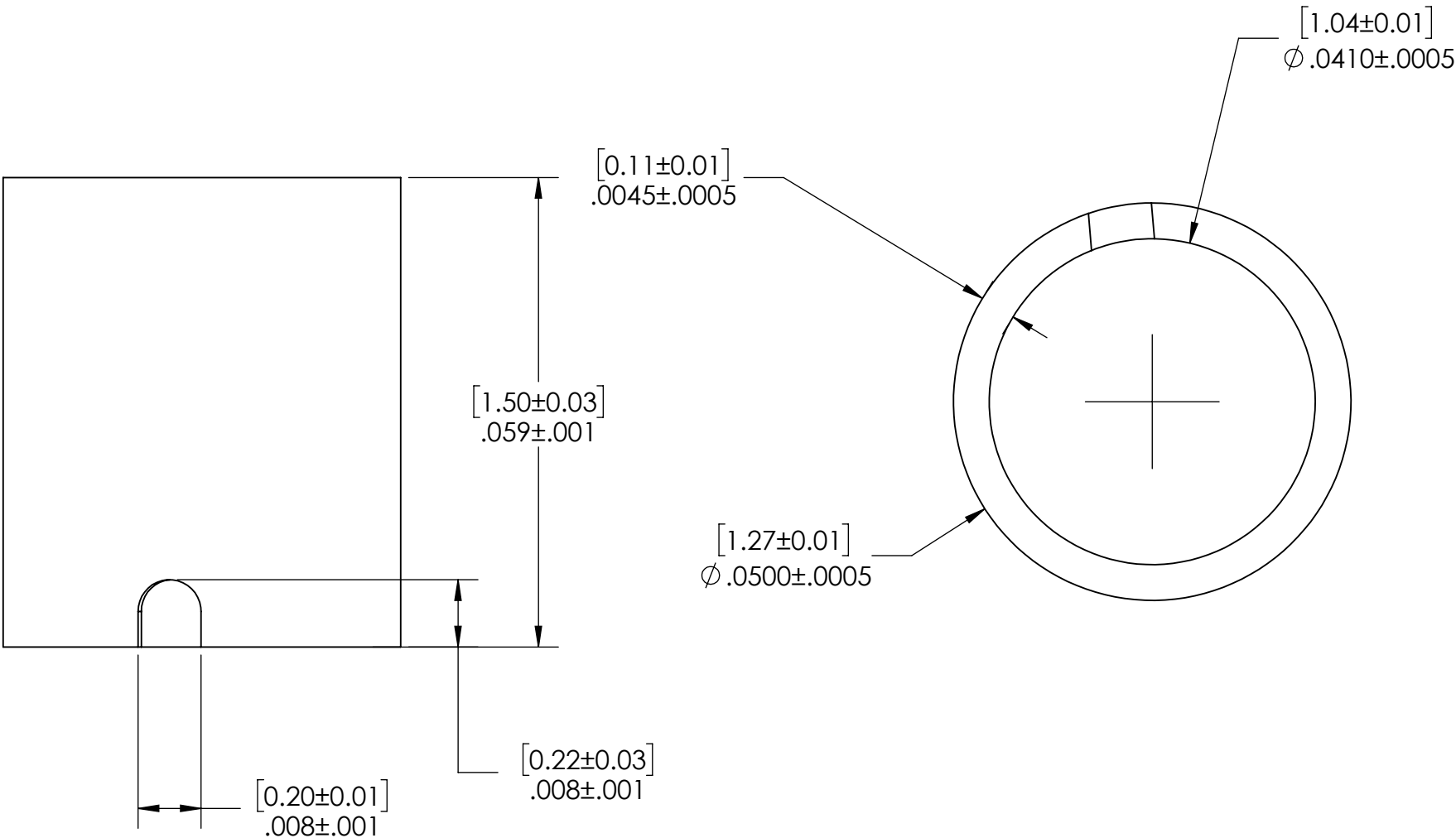
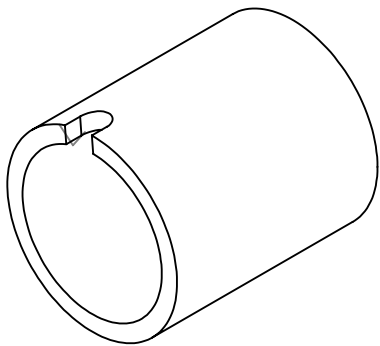
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REVISIONS				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	21-26	INITIAL RELEASE	J. GETSINGER	8/17/2021
2.0	21-37	RE-RELEASE	J. GETSINGER	10/13/2021



- NOTES:
- MATERIAL: MP35N
 - PARTS SHALL BE FREE OF BURRS AND SHARP EDGES

NEXT ASSEMBLY

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE:		
		PROXIMAL CONTACT - 1.5MM		
		PROPRIETARY AND CONFIDENTIAL		
		THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		
SIZE	DWG. NO.	REV		
B	6090	2.0		
SCALE: 50:1		SHEET 1 OF 1		

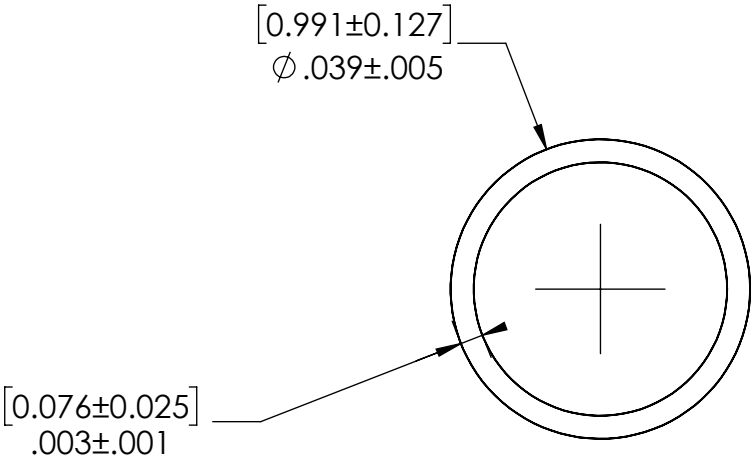
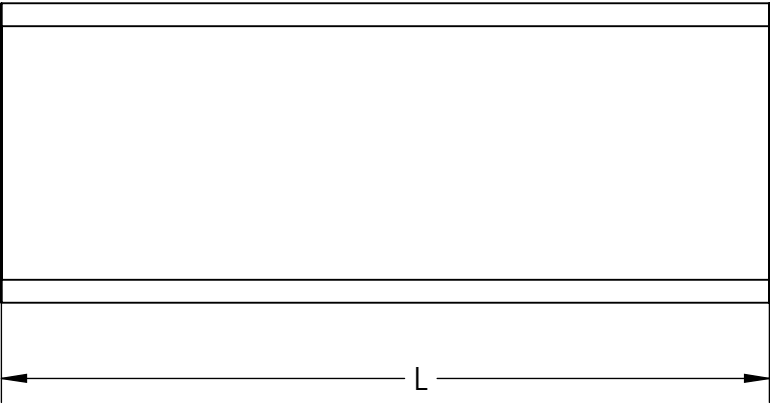
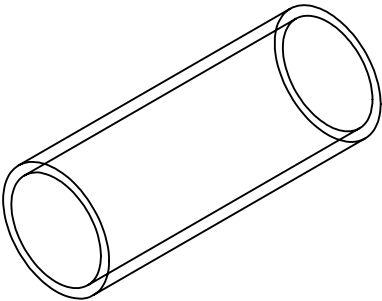
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Revisions				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	22-28	INITIAL RELEASE	J. GETSINGER	4NOV22



- NOTES:
1. MATERIAL: PEEK
 2. LENGTH (L) WILL BE DISTINGUISHED ON PO

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE: PEEK SINGLE LUMEN TUBE		
		SIZE	DWG. NO.	REV
		B	6153	1.0
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SCALE: 40:1		SHEET 1 OF 1

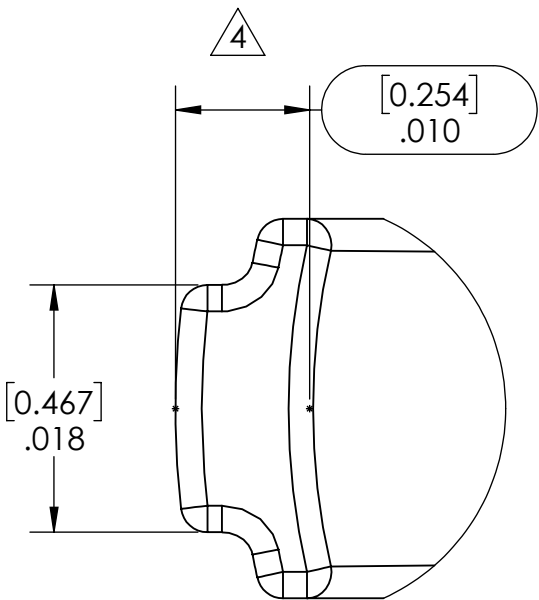
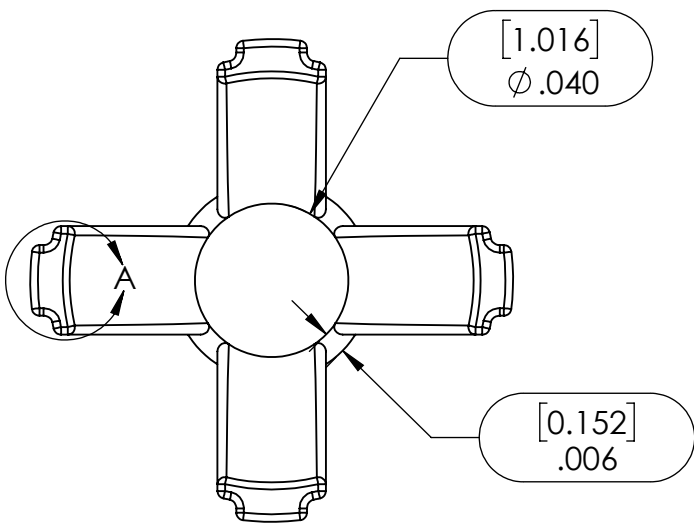
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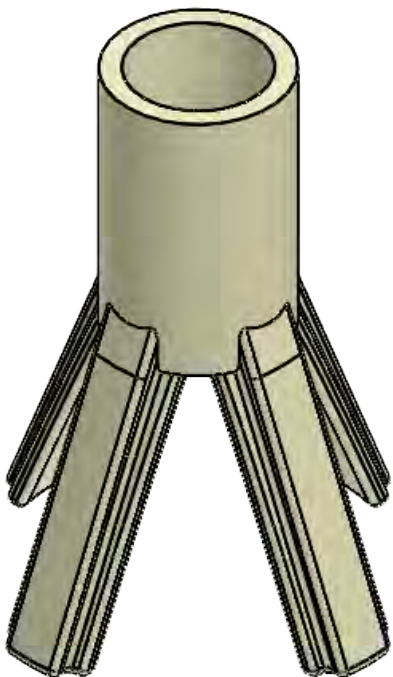
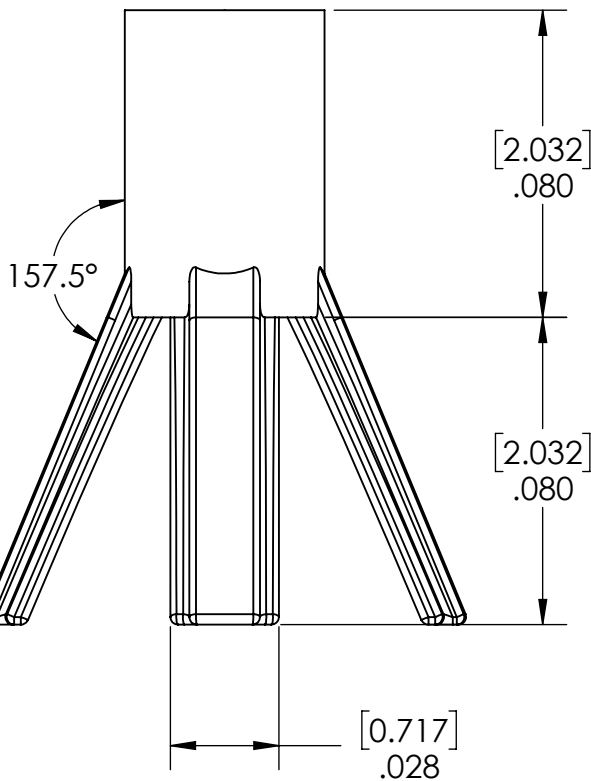
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1

REVISIONS				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	21-45	INITIAL RELEASE	J. GETSINGER	6DEC2021
2.0	22-33	INCREASED THICKNESS OF TINE FROM 0.004" TO 0.006"	J. GETSINGER	13DEC2022
3.0	22-36	CORRECTED I.D. TO MATCH REV 1.1	J. WELLS	04JAN2023
4.0	23-10	ADDED "RIBBED" FEATURE TO WINGS	F. ROBERTS	22MAR2023




DETAIL A
SCALE 70 : 1



- NOTES:
1. MATERIAL: PELLETHANE 75D
 2. NO BURRS, SINK MARKS, SCRATCHES, OR OTHER DEFECTS THAT MAY BE VISIBLE
 3. NO FLASHES GREATER THAN 0.2 MM
 4. MANUAL OR AIR EXTRACTION (NO EXTRACTION MARKS)
 5. MEASURE THE 3 (CRITICAL DIMENSIONS) OF THE FIRST 10 AND LAST 10 OF EACH LOT

Next Assembly
3008, 3011

UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING PROPRIETARY AND CONFIDENTIAL THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		TITLE:	
		TINE	
		SIZE B	DWG. NO. 6222
		SCALE: 20:1	REV 4.0
		SHEET 1 OF 1	

	Drawing No:	7008	Revision:	1.0
	Part No:	7008	Created By:	C. Mannarino
	Part Description 1:	Epoxy, EPO-Tek 301		
	Part Description 2:	Epoxy Technology EPO-Tek 301		
Med-Ally,LLC 2040 Bushy Park Road, North Bldg 6 Goose Creek, SC 29445	Supplier Part No:	EPO-Tek 301		
	Supplier Name:	Epoxy Technology		
	Specification Control Drawing			

Rev	ECO Number	Description	Date
1.0	19-52	Initial release	12 Nov 19



EPO-TEK® 301

Technical Data Sheet
For Reference Only
Spectrally Transparent Epoxy

Date: September 2017
Rev: X
No. of Components: Two
Mix Ratio by Weight: 20 : 5
Specific Gravity: Part A: 1.15 Part B: 0.87
Pot Life: 1-2 Hours
Shelf Life- Bulk: One year at room temperature

Recommended Cure: 65°C / 2 Hours

Minimum Alternative Cure(s):
May not achieve performance properties listed below
85°C / 1 Hour
23°C / 24 Hours

NOTES:

- Container(s) should be kept closed when not in use.
- Filled systems should be stirred thoroughly before mixing and prior to use.
- Performance properties (rheology, conductivity, others) of the product may vary from those stated on the data sheet when bi-pak/syringe packaging or post-processing of any kind is performed. Epoxy's warranties shall not apply to any products that have been reprocessed or repackaged from Epoxy's delivered status/container into any other containers of any kind, including but not limited to syringes, bi-paks, cartridges, pouches, tubes, capsules, films or other packages.
- Syringe packaging will impact initial viscosity and effective pot life, potentially beyond stated parameters.
- TOTAL MASS SHOULD NOT EXCEED 25 GRAMS

Product Description: EPO-TEK® 301 is a two component, room temperature curing epoxy featuring very low viscosity, and excellent optical-mechanical properties.

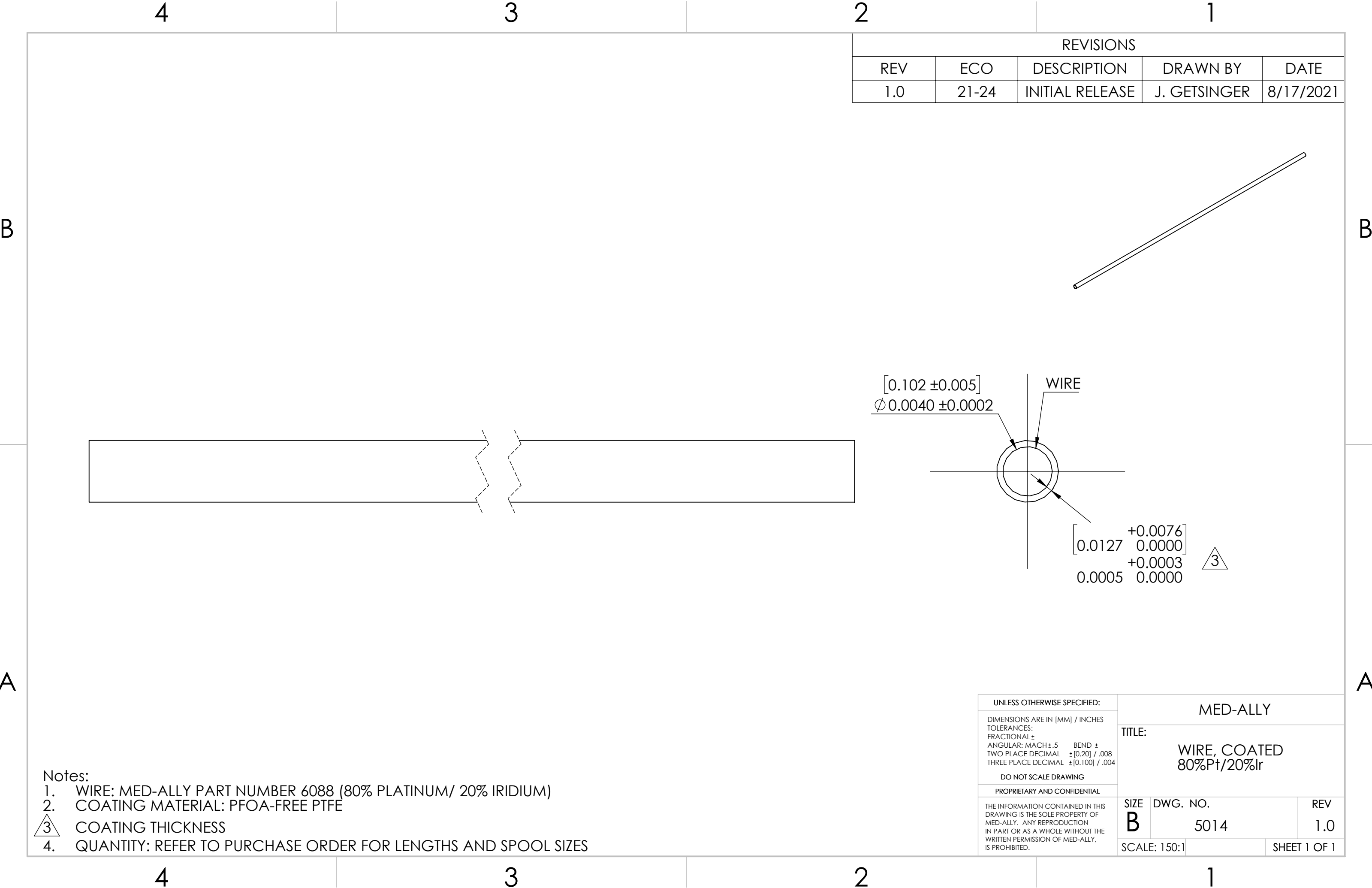
Typical Properties: Cure condition: Varies as required. Different batches, conditions & applications yield differing results. Data below is not guaranteed. To be used as a guide only, not as a specification. * denotes test on lot acceptance basis

PHYSICAL PROPERTIES:			
* Color (before cure):	Part A: Clear/Colorless	Part B: Clear/Colorless	
* Consistency:	Pourable liquid		
* Viscosity (23°C) @ 100 rpm:	100 - 200	cPs	
Thixotropic Index:	N/A		
* Glass Transition Temp:	≥ 65	°C (Dynamic Cure: 20-200°C/ISO 25 Min; Ramp -10-200°C @20°C/Min)	
Coefficient of Thermal Expansion (CTE):			
Below Tg:	39	x 10 ⁻⁶ in/in°C	
Above Tg:	98	x 10 ⁻⁶ in/in°C	
Shore D Hardness:	85		
Lap Shear @ 23°C:	> 2,000	psi	
Die Shear @ 23°C:	≥ 10	Kg	3,556 psi
Degradation Temp:	430	°C	
Weight Loss:			
@ 200°C:	0.12	%	
@ 250°C:	0.13	%	
@ 300°C:	0.39	%	
Suggested Operating Temperature:	< 300	°C (Intermittent)	
Storage Modulus:	436,249	psi	
* Particle Size:	N/A		
ELECTRICAL AND THERMAL PROPERTIES:			
Thermal Conductivity:	N/A		
Volume Resistivity @ 23°C:	≥ 1 x 10 ¹³	Ohm-cm	
Dielectric Constant (1KHz):	4.00		
Dissipation Factor (1KHz):	0.016		
OPTICAL PROPERTIES @ 23°C:			
Spectral Transmission:	≥ 99% @ 382-980	nm	
	≥ 97% @ 980-1,640	nm	
	≥ 95% @ 1,640-2,040	nm	
Refractive Index:	1.519 @ 589	nm	

Epoxyes and Adhesives for Demanding Applications™

This information is based on data and tests believed to be accurate. Epoxy Technology, Inc. makes no warranties (expressed or implied) as to its accuracy and assumes no liability in connection with any use of this product.

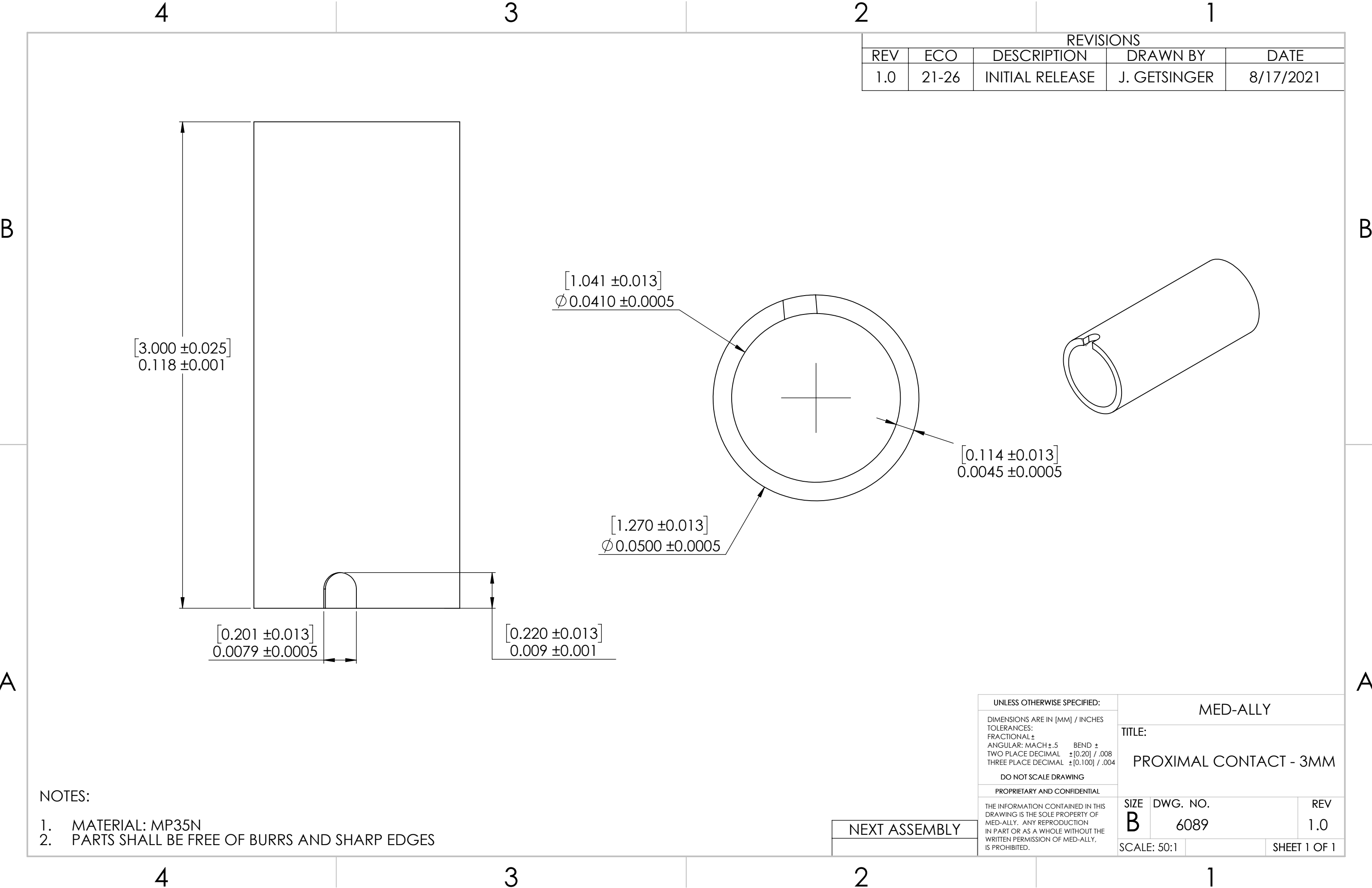
EPOXY TECHNOLOGY, INC.
14 FORTUNE DRIVE, BILLERICA, MA 01821 (978) 667-3805, FAX (978) 663-9782
www.epotek.com



REVISIONS				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	21-24	INITIAL RELEASE	J. GETSINGER	8/17/2021

- Notes:
1. WIRE: MED-ALLY PART NUMBER 6088 (80% PLATINUM/ 20% IRIIDIUM)
 2. COATING MATERIAL: PFOA-FREE PTFE
 - $\triangle 3$ 3. COATING THICKNESS
 4. QUANTITY: REFER TO PURCHASE ORDER FOR LENGTHS AND SPOOL SIZES

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL \pm ANGULAR: MACH $\pm .5$ BEND \pm TWO PLACE DECIMAL $\pm [0.20] / .008$ THREE PLACE DECIMAL $\pm [0.100] / .004$ DO NOT SCALE DRAWING		TITLE: WIRE, COATED 80%Pt/20%Ir		
		SIZE	DWG. NO.	REV
		B	5014	1.0
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SCALE: 150:1		SHEET 1 OF 1



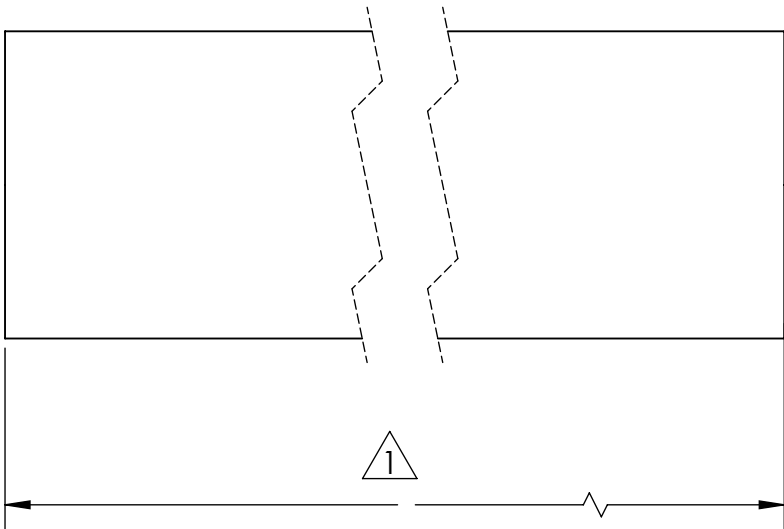
REVISIONS				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	21-26	INITIAL RELEASE	J. GETSINGER	8/17/2021

- NOTES:
- MATERIAL: MP35N
 - PARTS SHALL BE FREE OF BURRS AND SHARP EDGES

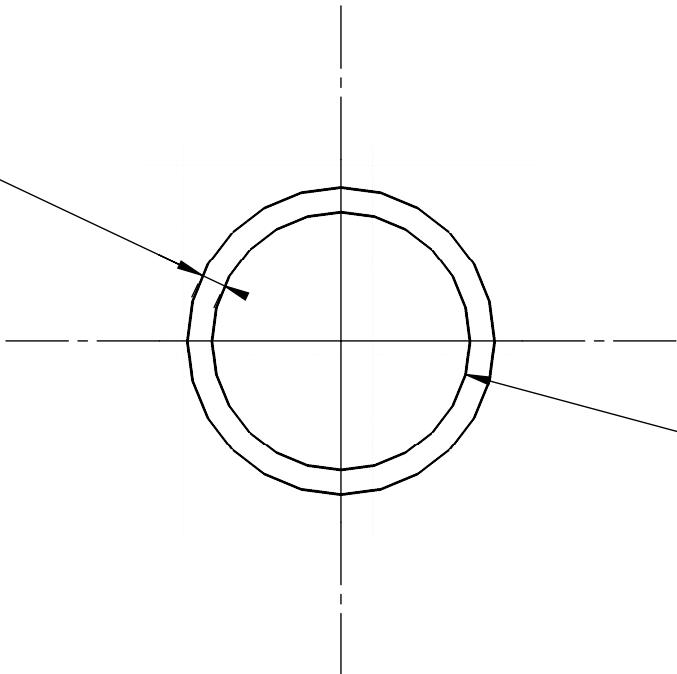
NEXT ASSEMBLY

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE: PROXIMAL CONTACT - 3MM		
		SIZE	DWG. NO.	REV
		B	6089	1.0
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SCALE: 50:1	SHEET 1 OF 1	

REVISIONS				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	21-24	INITIAL RELEASE	J. GETSINGER	12AUG21
2.0	21-45	REMOVED MATERIAL FROM NAME, CHANGED ID FROM 0.039 TO 0.042 AND DIMENSIONED WALL INSTEAD OF OD	J.GETSINGER	6DEC21



[0.10±0.04]
.0040±.0015



[1.07±0.04]
Ø.0420±.0015

- NOTES:
- 1 REFER TO TUBING LENGTH SPECIFIED ON PURCHASE ORDER
 2. MATERIAL: POLYURETHANE, 55D

UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING PROPRIETARY AND CONFIDENTIAL THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		TITLE: OUTER TUBING	
		SIZE B	REV 2.0
		DWG. NO. 6085	DATE 12AUG21
		SCALE: 32:1	SHEET 1 OF 1

REVISIONS				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	21-24	INITIAL RELEASE	J. GETSINGER	12AUG21
2.0	21-31	ADDED TUBE 6084-4	J. GETSINGER	7SEPT21
3.0	21-45	REMOVED MATERIAL FROM NAME AND DIMENSIONED WALL INSTEAD OF OD	J. GETSINGER	6DEC21

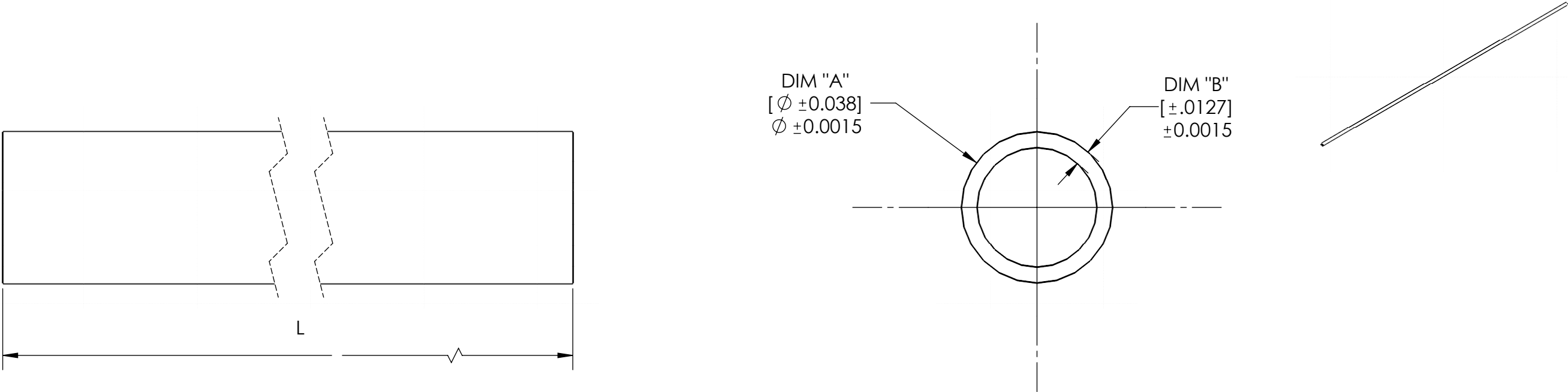


TABLE A			
PART NUMBER	DIM "A"	DIM "B"	LENGTH (L)
6084-1	0.041 [1.04]	0.0043 [.12]	SPECIFIED IN PO
6084-2	0.052 [1.32]	0.0065 [0.17]	SPECIFIED IN PO
6084-3	0.051 [1.30]	0.0093 [0.24]	SPECIFIED IN PO
6084-4	0.039 [0.99]	0.0033 [0.083]	SPECIFIED IN PO

Notes:
1. MATERIAL: POLYURETHANE, 80A

UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE: INNER TUBING	
		PROPRIETARY AND CONFIDENTIAL	
		THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.	
		SIZE B	DWG. NO. 6084
SCALE: 32:1		REV 3.0	SHEET 1 OF 1

REVISIONS				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	21-40	INITIAL RELEASE	J. GETSINGER	22OCT2021
2.0		ADDED LENGTH TABLE AND WIRE QUANTITY NEEDED TO MAKE THE COILS	J. GETSINGER	13APR2023

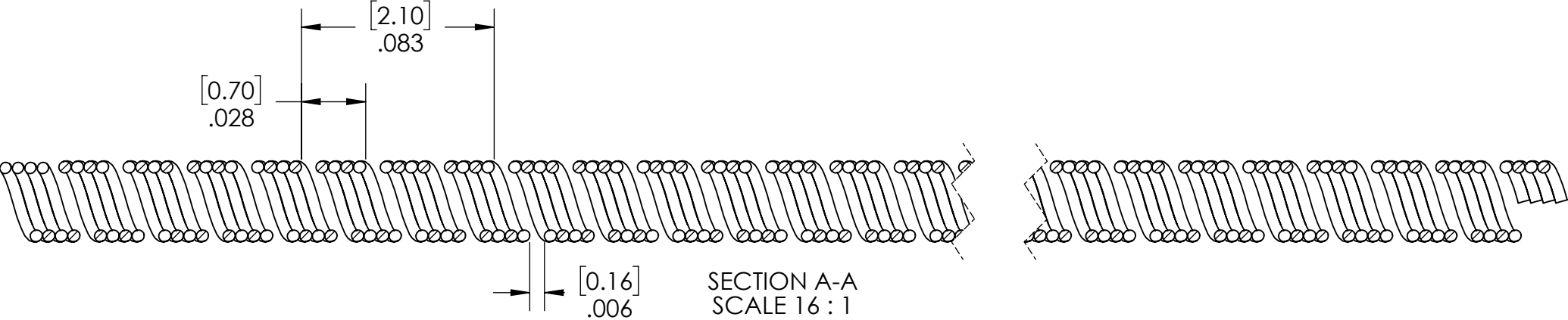
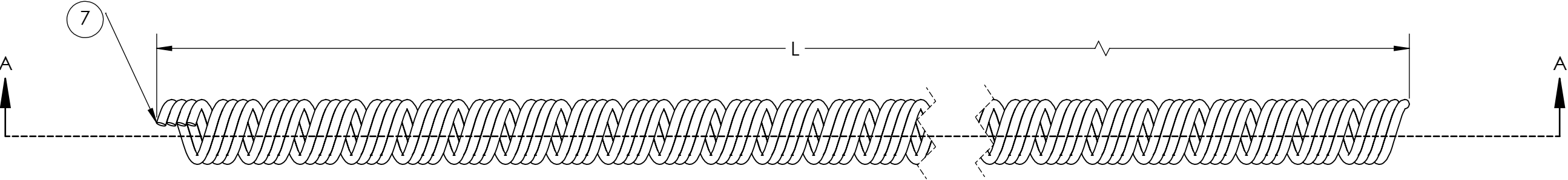


TABLE A		
PART NUMBER	LENGTH (MM)	REQUIRED PN 5014 TOTAL LENGTH (MM)[REF]
5019-350	350	4472
5019-400	400	5110
5019-500	500	6388

- NOTES:
- MATERIAL: PART NUMBER 5014 WIRE, COATED, 80% PT/20% IR
 - SEE TABLE A FOR DIFFERENT LENGTHS OF COILS (L) AND WIRE NEEDED TO MAKE THE COILS

NEXT ASSEMBLY
3009, 3011

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL \pm ANGULAR: MACH $\pm .5$ BEND \pm TWO PLACE DECIMAL $\pm [0.20] / .008$ THREE PLACE DECIMAL $\pm [0.100] / .004$ DO NOT SCALE DRAWING		TITLE: 4 FILAR COIL		
PROPRIETARY AND CONFIDENTIAL		SIZE B	DWG. NO. 5019	REV 2.0
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SCALE: 4:1		SHEET 1 OF 1

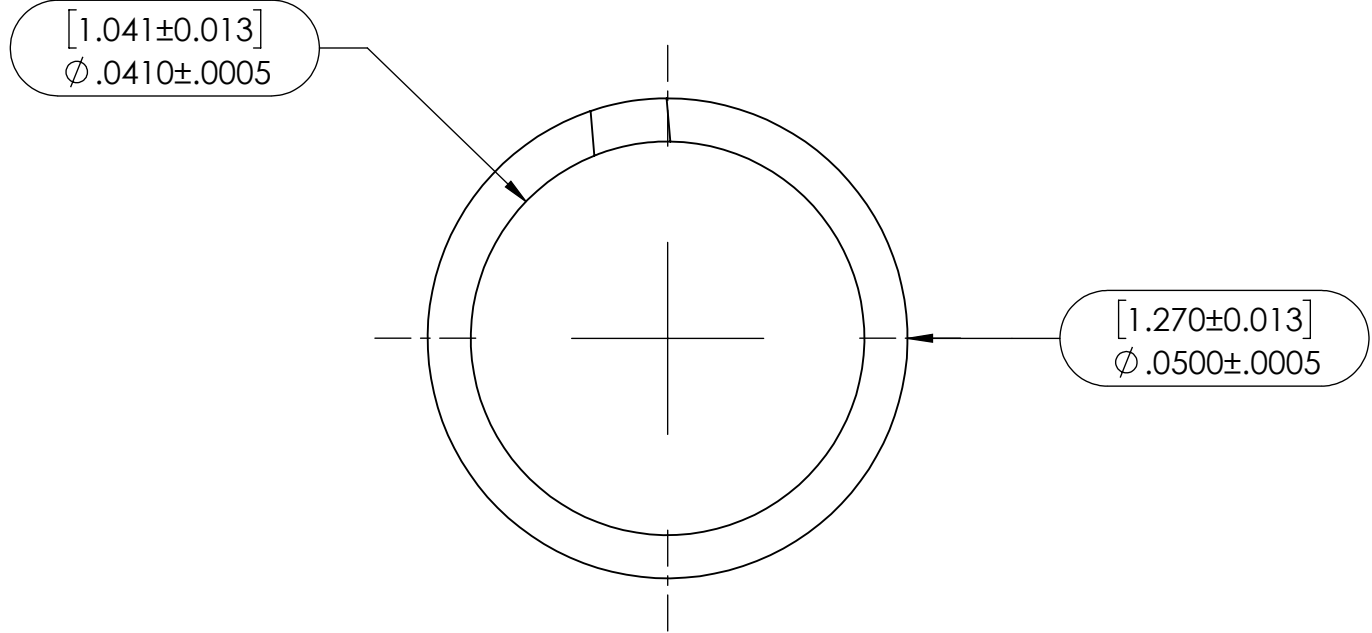
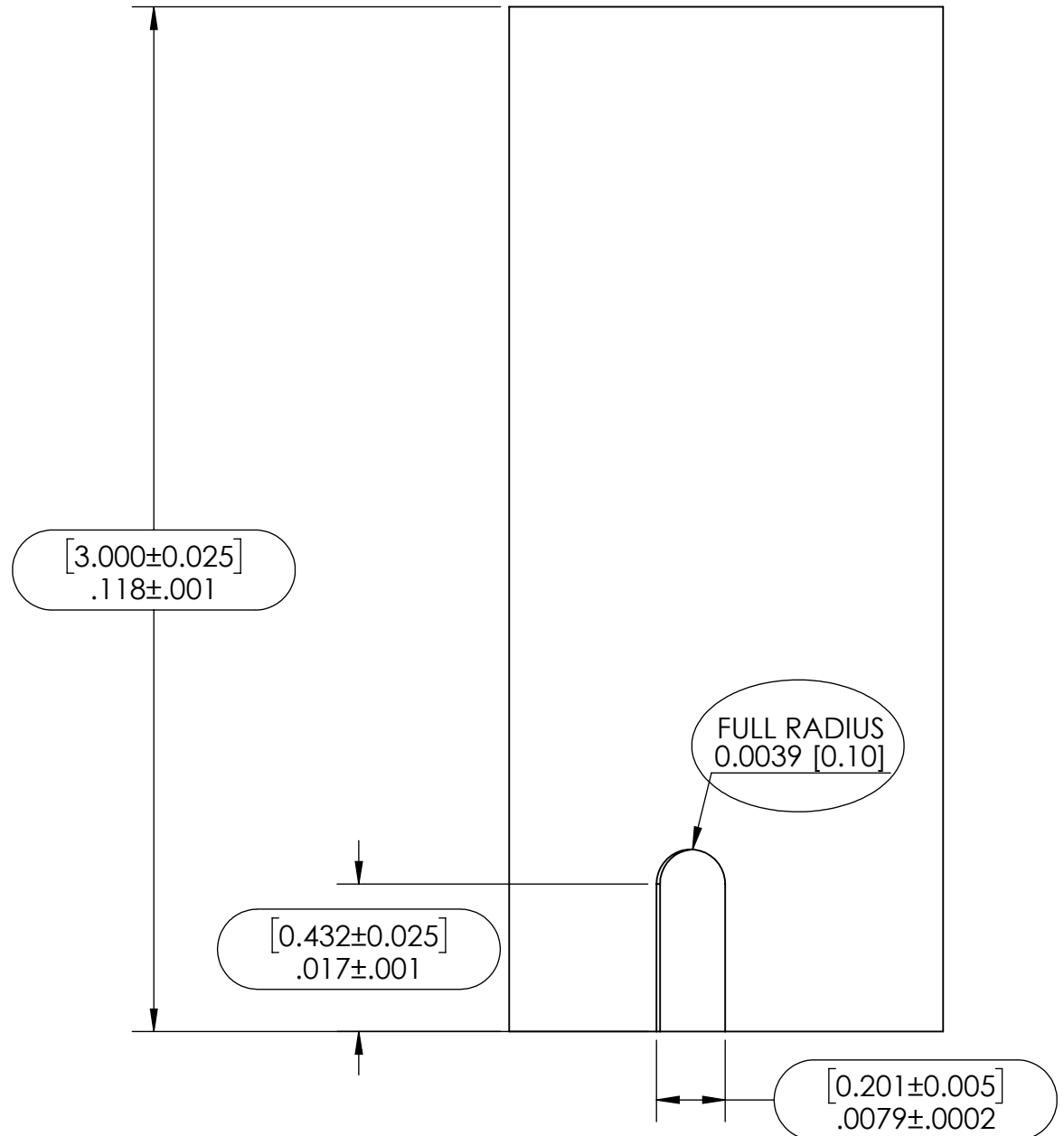
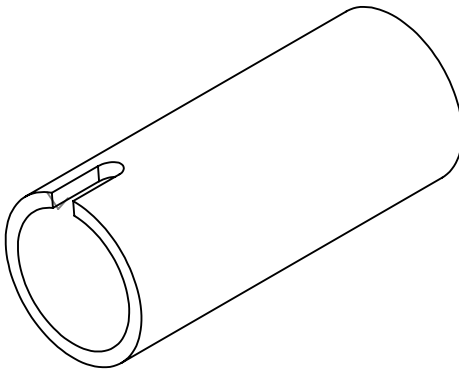
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B

A

A


REVISIONS				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	21-22	INITIAL RELEASE	J. GETSINGER	7/30/21
2.0	21-37	RE-RELEASE	J. GETSINGER	10/13/2021



- NOTES:
- 1. MATERIAL: 90%Pt/10%Ir
 - 2. PARTS SHALL BE FREE OF BURRS AND SHARP EDGES
 - 3. SEE TABLE A FOR DIFFERENT LENGTHS OF ELECTRODES
 - 4. CRITICAL DIMENSIONS ARE CIRCLED

TABLE A	
PART NUMBER	LENGTHS
6081-3	0.118" [3 MM]
6081-1.5	0.059" [1.50 MM]

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING PROPRIETARY AND CONFIDENTIAL THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		TITLE: ELECTRODE		
		SIZE B	DWG. NO. 6081	REV 2.0
		SCALE: 50:1		SHEET 1 OF 1

	Drawing No:	7065	Revision:	1.0
	Part No:	7065	Created By:	J. Getsinger
	Part Description 1:	Loctite M-11FL		
	Part Description 2:	Urethane Adhesive		
Med-Ally,LLC 2040 Bushy Park Road, North Bldg 6 Goose Creek, SC 29445	Supplier Part No:	235029		
	Supplier Name:	R.S. Hughes/Henkel		
	Specification Control Drawing			

Rev	ECO Number	Description	Date
1.0	ECO 22-28	Initial Release	4Nov22



Technical Information

Agency Approvals / Certificates / Specifications	ISO 10993
Cure Type	Room Temperature (Ambient) Cure
Key Characteristics	Flexible: Highly Flexible, Peel Strength: High, Peel Strength: Viscosity: Low Viscosity
Number of Components	2 Part
Physical Form	Liquid
Shear Strength, Aluminum (etched)	1850.0 psi
Shear Strength, Steel (grit blasted)	160.0 psi
Substrates	Glass, Metal, Plastic
Mixed	
Color, Mixed	Clear; Ultra Clear
Resin	
Color, Resin	Clear
Hardener	
Color, Hardener	Clear

4

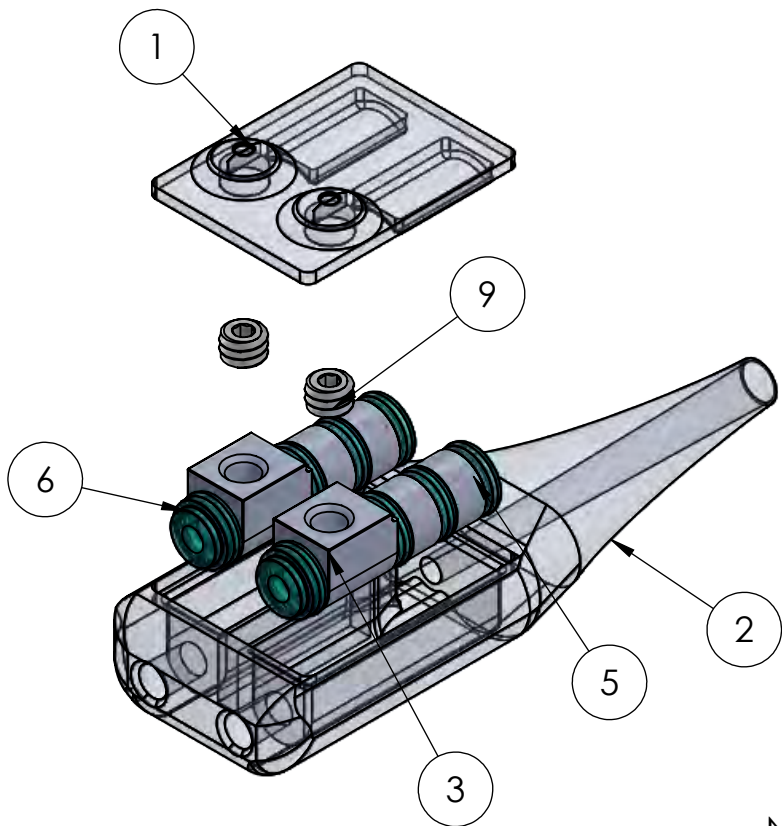
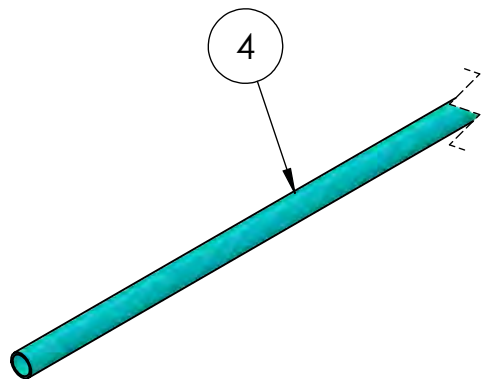
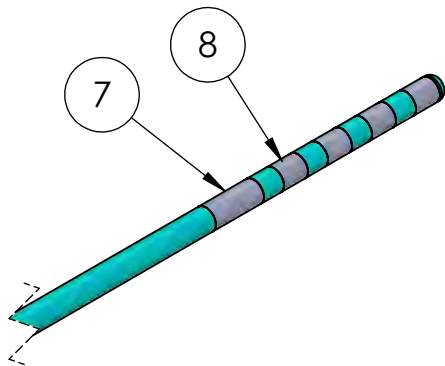
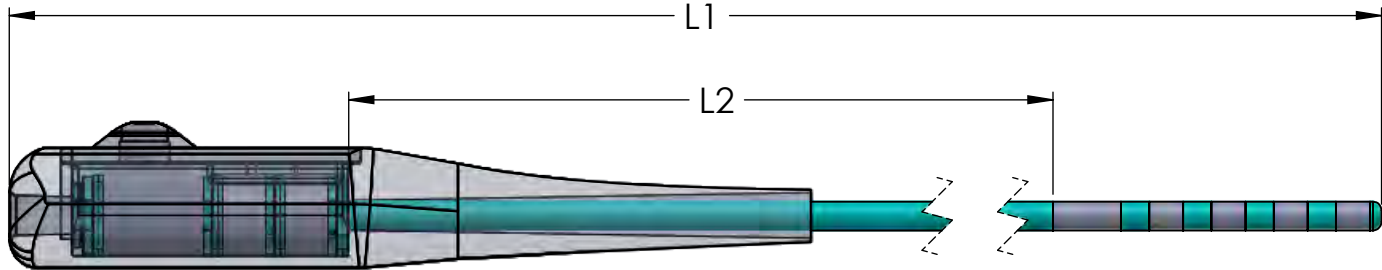
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2

1

REVISIONS

REV.	ECO	DESCRIPTION	DRAWN BY	DATE
0.1		INITIAL RELEASE	F. ROBERTS	16 MAR 2023



DRAFT

- NOTES:
1. L1 = 15cm - 100cm
 2. L2 = 12cm - 97cm
 3. 7073, SILICONE ADHESIVE, IS USED TO ADHERE 6172, INTERCONNECT TOP COVER, TO THE ASSEMBLY

Next Assembly

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	6172	Interconnect Top Cover	1
2	6173	Interconnnect Main	1
3	6005	Connector Block	2
4	6085	Outer Tubing	L2
5	7001	BALSEAL SYGNUS NEURO 2.8mm PITCH CONTACT	4
6	7002	BALSEAL SYGNUS NEURO SEAL	8
7	6089	3mm Contact	1
8	6090	1.5mm Contact	3
9	6003	#2-56 Setscrew	2
10	7065	Loctite M-11FL Urethane Adhesive	A/R
11	7073	Silicone Adhesive, MED-2000	A/R
12	7008	Epoxy, EPO-TEK 301	A/R
13	6153	PEEK Inner Tubing	14.5mm
14	5019	4 Filar Coil	L1

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN [MM] / INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ±.5 BEND ±
TWO PLACE DECIMAL ±[0.20] / .008
THREE PLACE DECIMAL ±[0.100] / .004

DO NOT SCALE DRAWING

PROPRIETARY AND CONFIDENTIAL

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MED-ALLY

TITLE:

Interconnect

SIZE
B

DWG. NO.
3019

REV
0.1

SCALE: 3:1

SHEET 1 OF 5

4

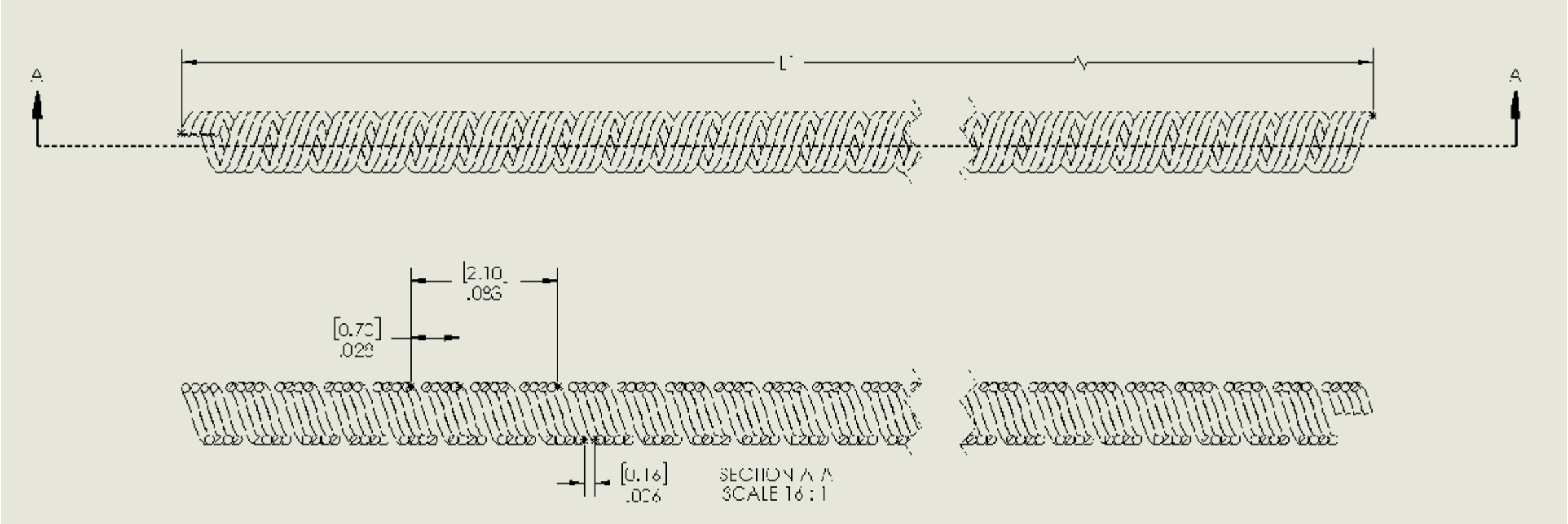
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UNLESS OTHERWISE SPECIFIED:		MED-ALLY				
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING					TITLE:	
					Title	
PROPRIETARY AND CONFIDENTIAL						
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SIZE	DWG. NO.	REV		
		B	DWG NO	Rev		
		SCALE: 5:1		SHEET 2 OF 5		

Next Assembly

Part No

4

3

2

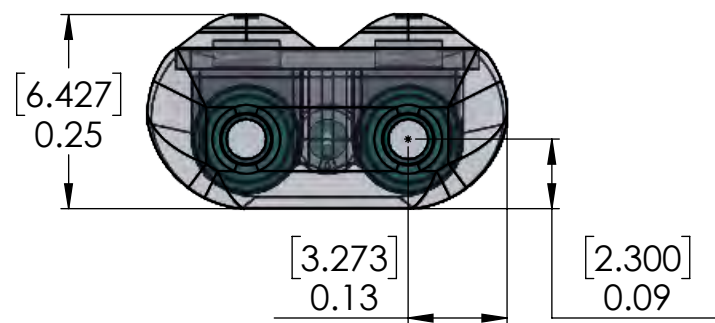
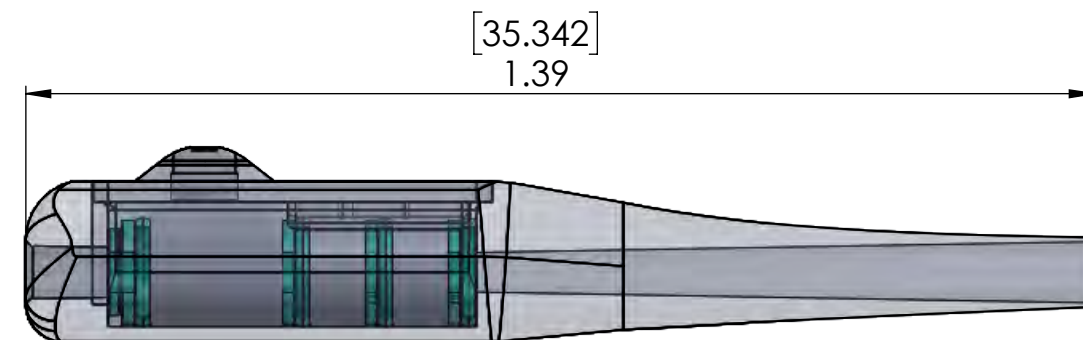
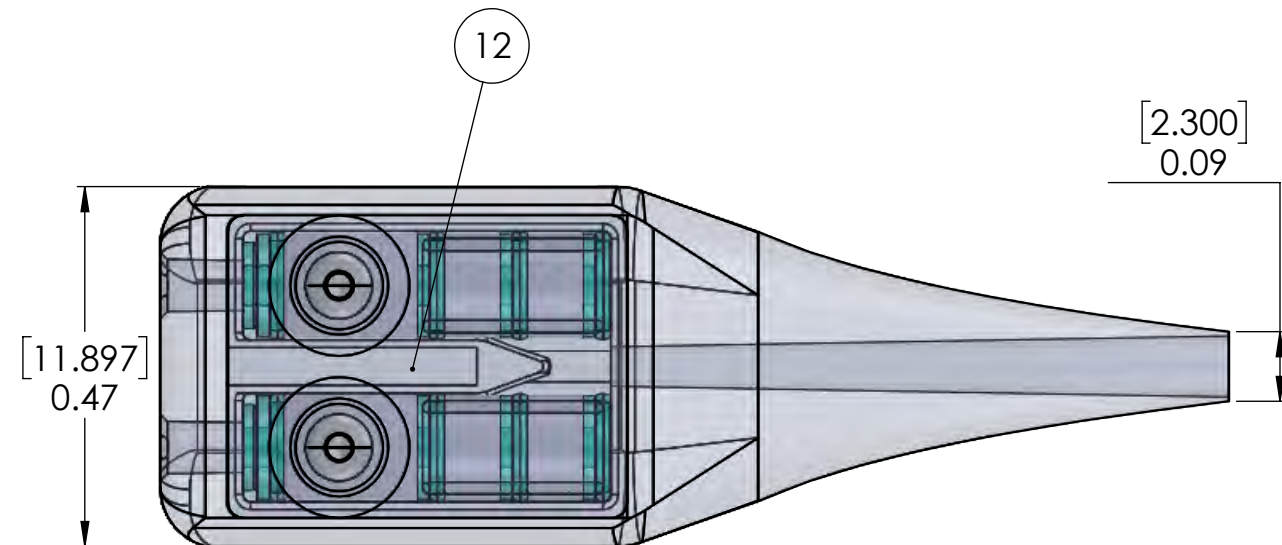
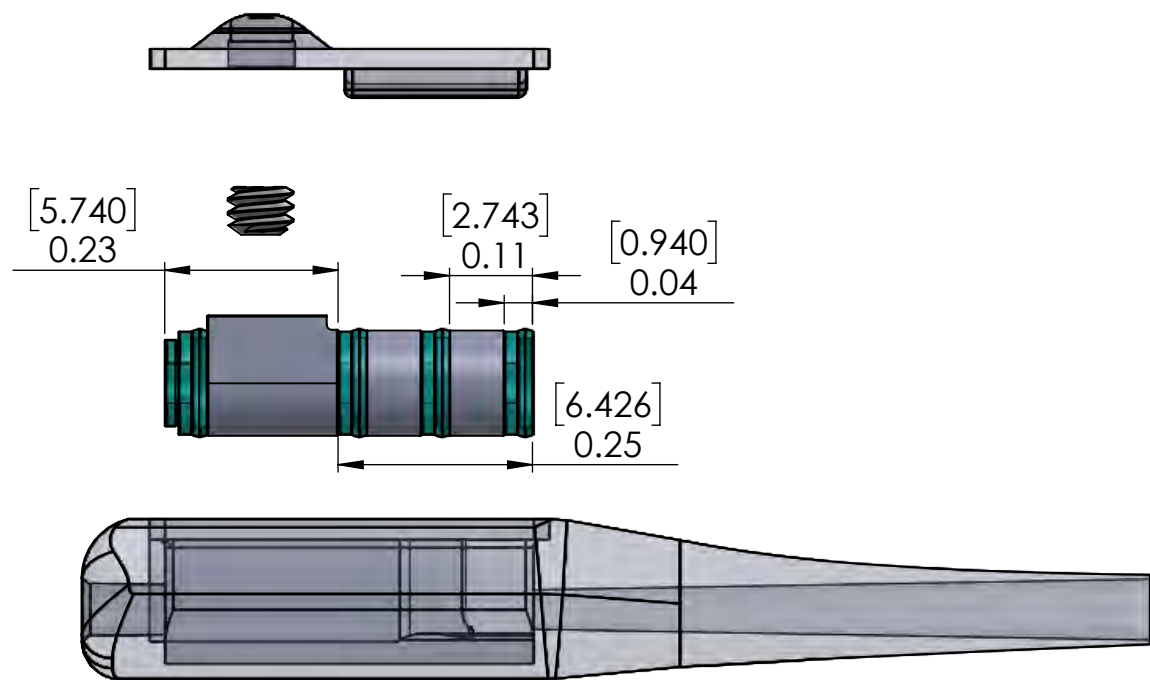
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B

A

B

A



DRAFT

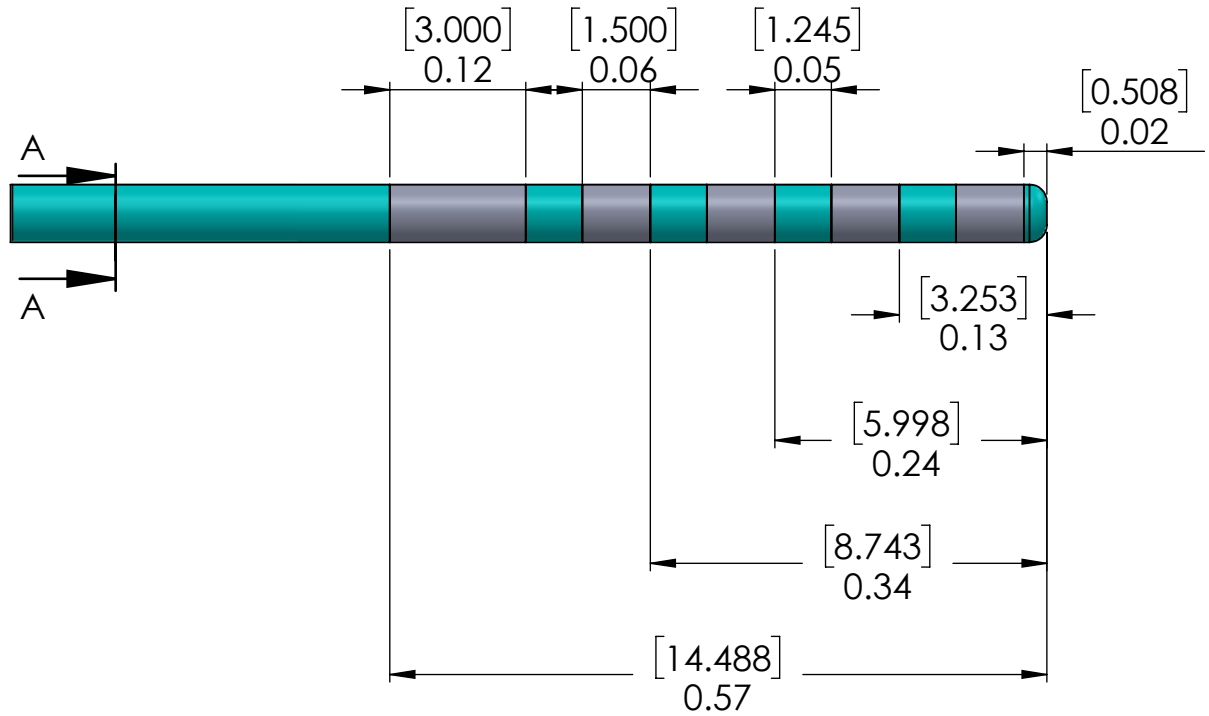
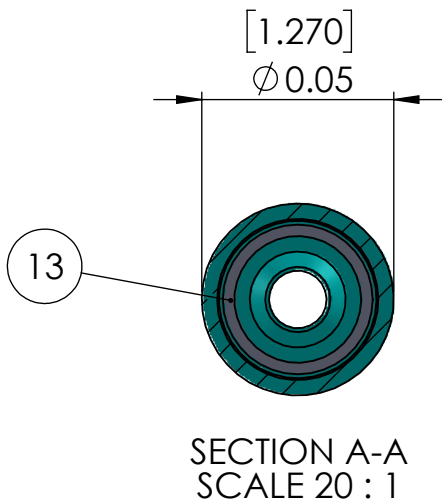
Notes:
1. 7008, Epoxy EPO-TEK 301 is added to cavity marked by balloon 12

Distal End

Next Assembly

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE: Interconnect		
PROPRIETARY AND CONFIDENTIAL				
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SIZE	DWG. NO.	REV
		B	3019	0.1
		SCALE: 4:1		SHEET 3 OF 5

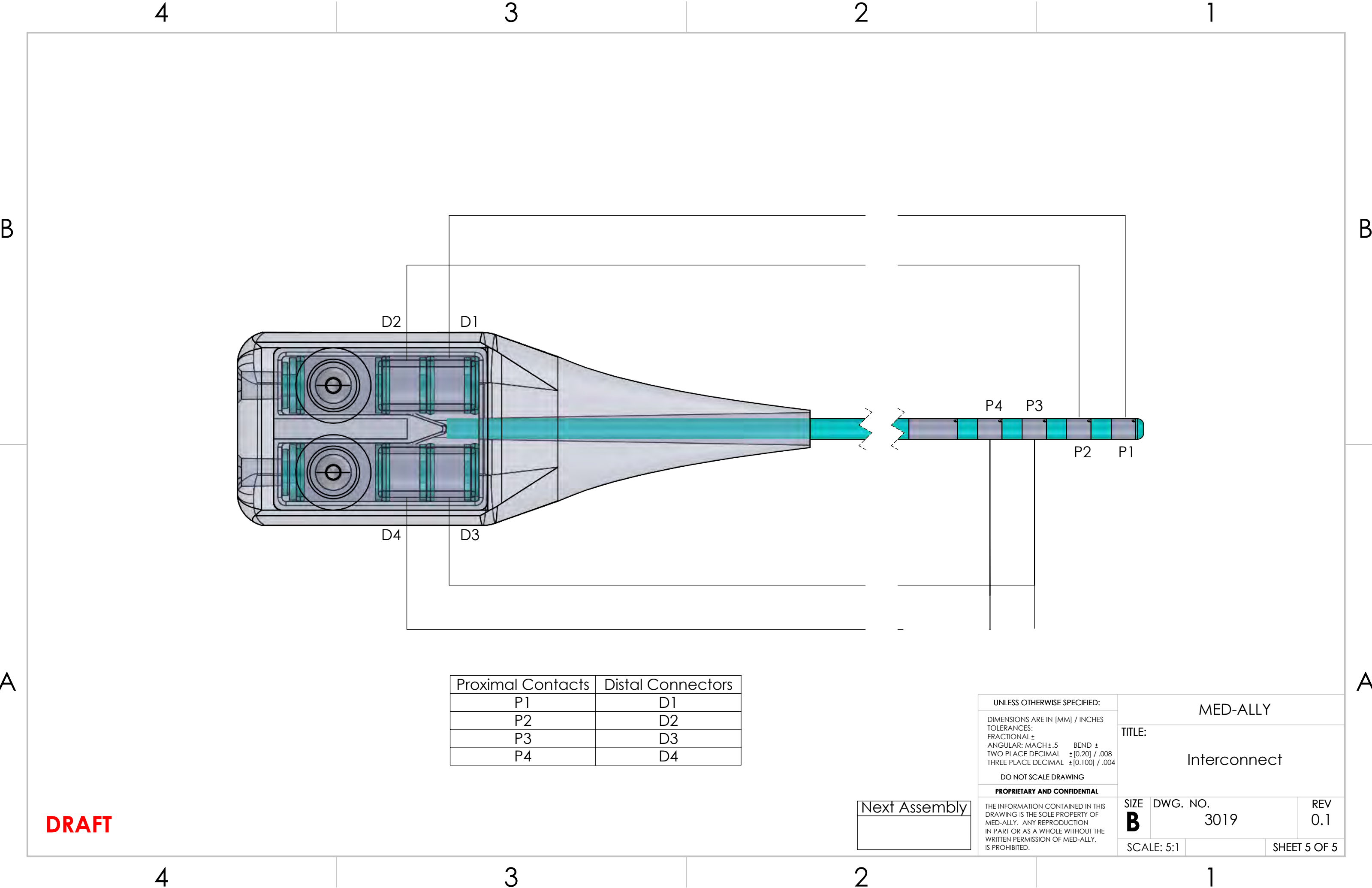
DRAFT



Proximal End

Next Assembly

UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE: Interconnect	
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.	SIZE B	DWG. NO. 3019	REV 0.1
	SCALE: 6:1		SHEET 4 OF 5



Proximal Contacts	Distal Connectors
P1	D1
P2	D2
P3	D3
P4	D4

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES				
TOLERANCES:				
FRACTIONAL ±				
ANGULAR: MACH ±.5 BEND ±		TITLE: Interconnect		
TWO PLACE DECIMAL ±[0.20] / .008				
THREE PLACE DECIMAL ±[0.100] / .004				
DO NOT SCALE DRAWING				
PROPRIETARY AND CONFIDENTIAL				
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SIZE	DWG. NO.	REV
		B	3019	0.1
		SCALE: 5:1		SHEET 5 OF 5

Next Assembly

DRAFT

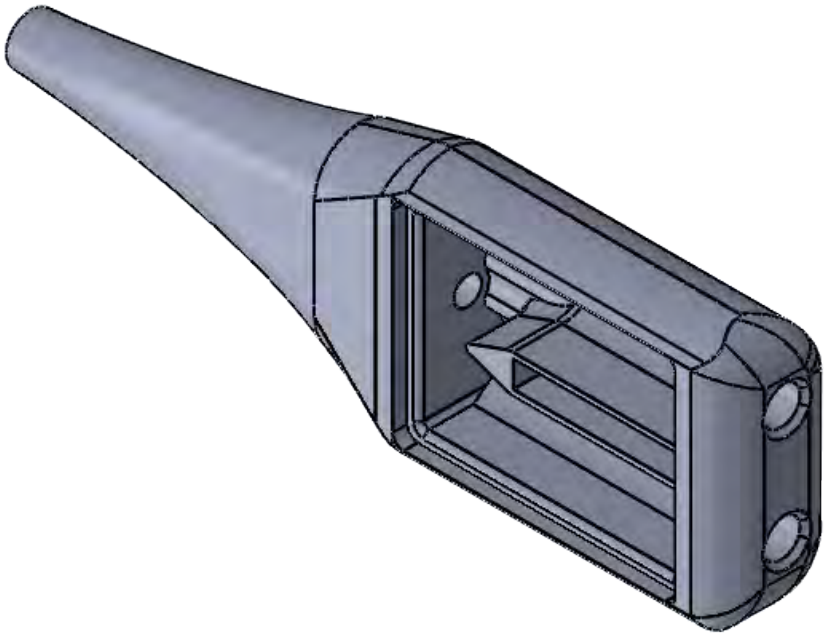
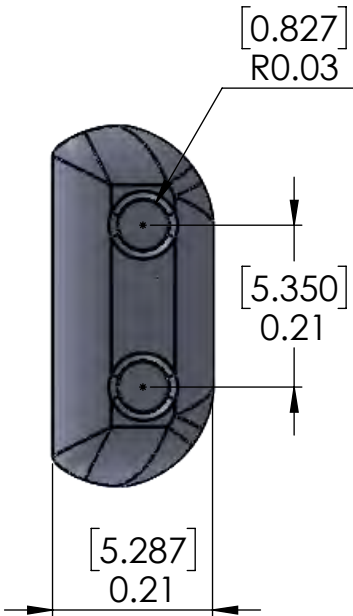
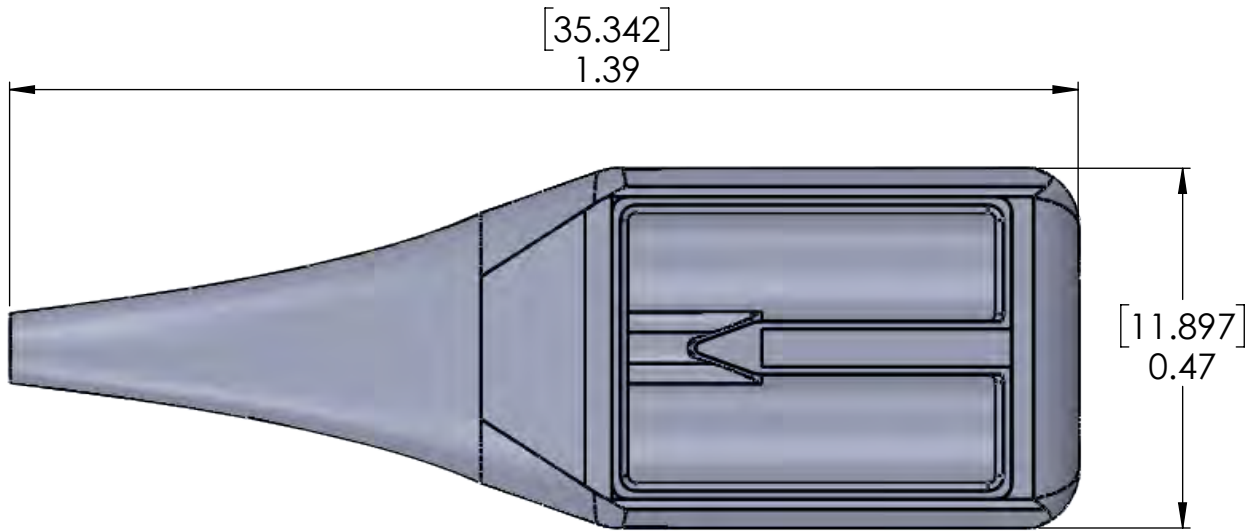
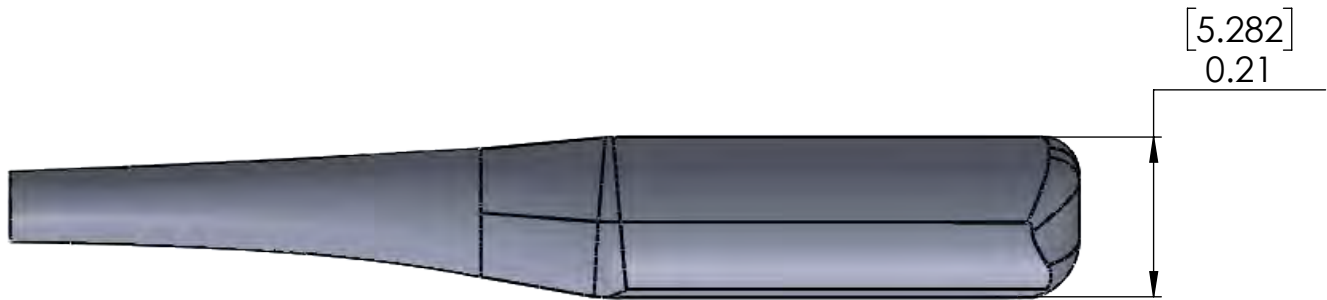
4

3

2

1

DRAFT



Model Number: 8278, Innerconnect Main, Rev 1.0

Next Assembly
3019

UNLESS OTHERWISE SPECIFIED:		MED-ALLY TITLE: Interconnect Main		
DIMENSIONS ARE IN [MM] / INCHES				
TOLERANCES:				
FRACTIONAL ±				
ANGULAR: MACH ±.5 BEND ±				
TWO PLACE DECIMAL ±[0.20] / .008				
THREE PLACE DECIMAL ±[0.100] / .004				
DO NOT SCALE DRAWING				
PROPRIETARY AND CONFIDENTIAL				
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SIZE	DWG. NO.	REV
		B	6173	0.1
		SCALE: 4:1		SHEET 1 OF 2

4

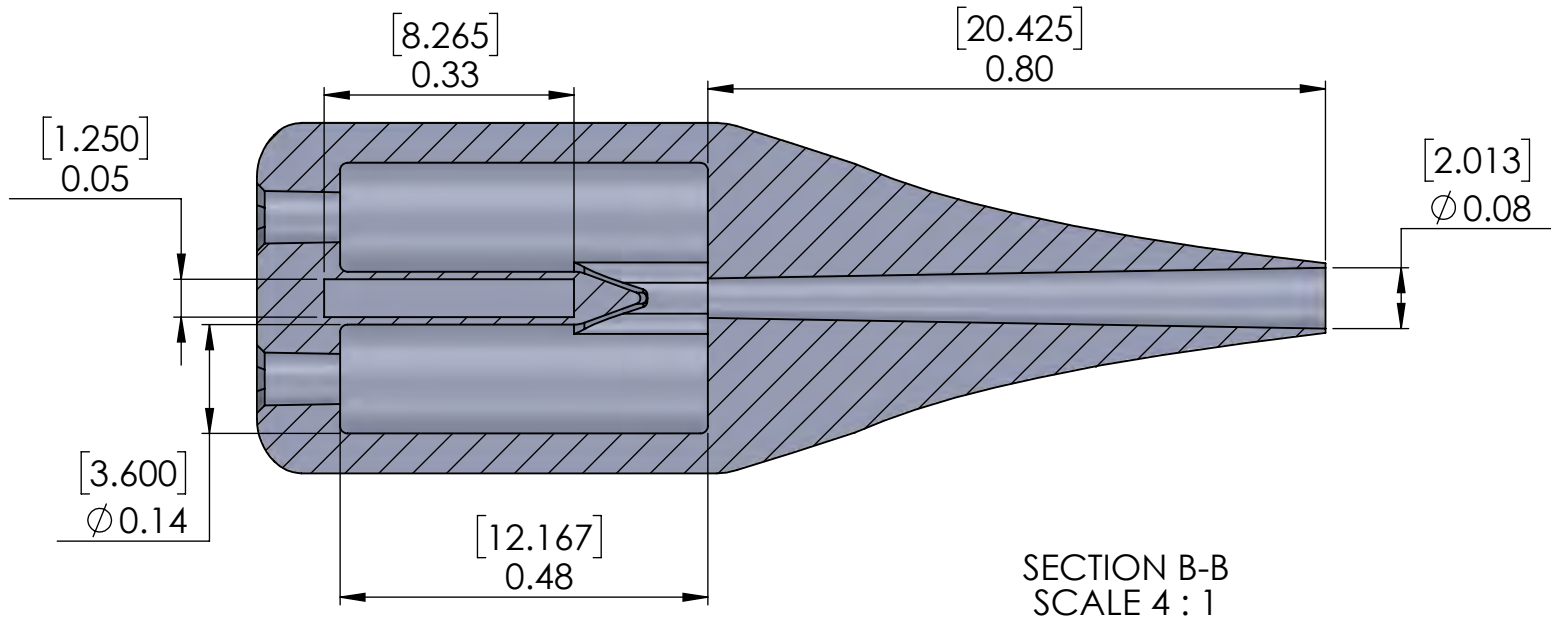
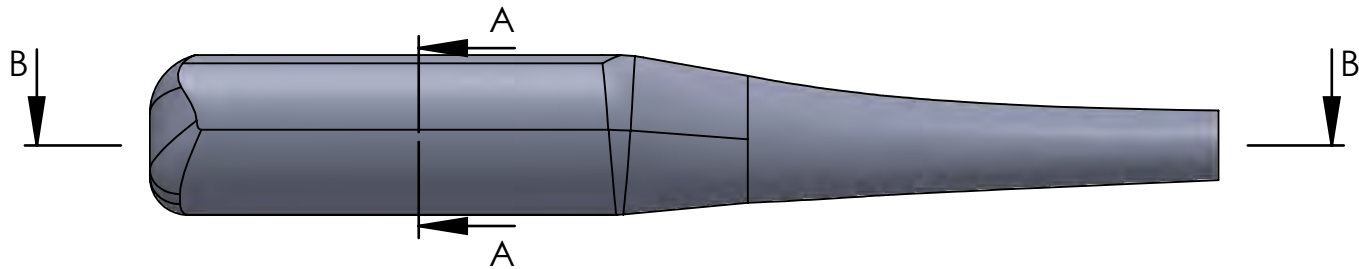
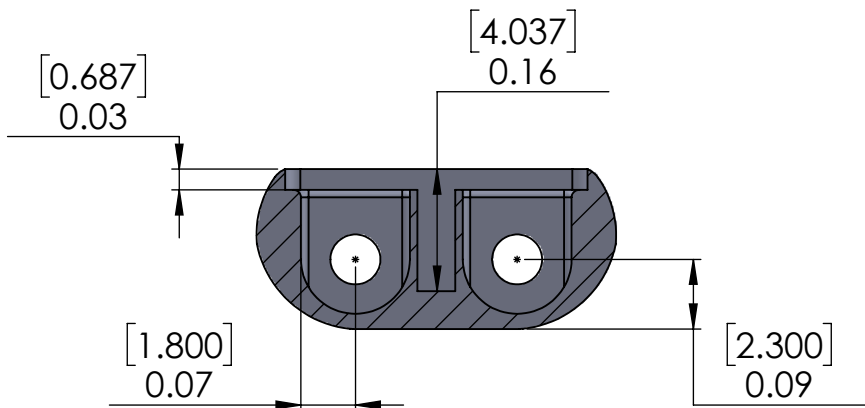
3

2

1

B

B



DRAFT

SECTION B-B
SCALE 4 : 1

UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES		TITLE:	
TOLERANCES:		Interconnect Main	
FRACTIONAL \pm			
ANGULAR: MACH \pm .5			
BEND \pm			
TWO PLACE DECIMAL \pm [0.20] / .008			
THREE PLACE DECIMAL \pm [0.100] / .004			
DO NOT SCALE DRAWING			
PROPRIETARY AND CONFIDENTIAL			
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SIZE	REV
		B	0.1
		DWG. NO.	
		6173	
		SCALE: 4:1	SHEET 2 OF 2

Next Assembly
3019

4

3

2

1

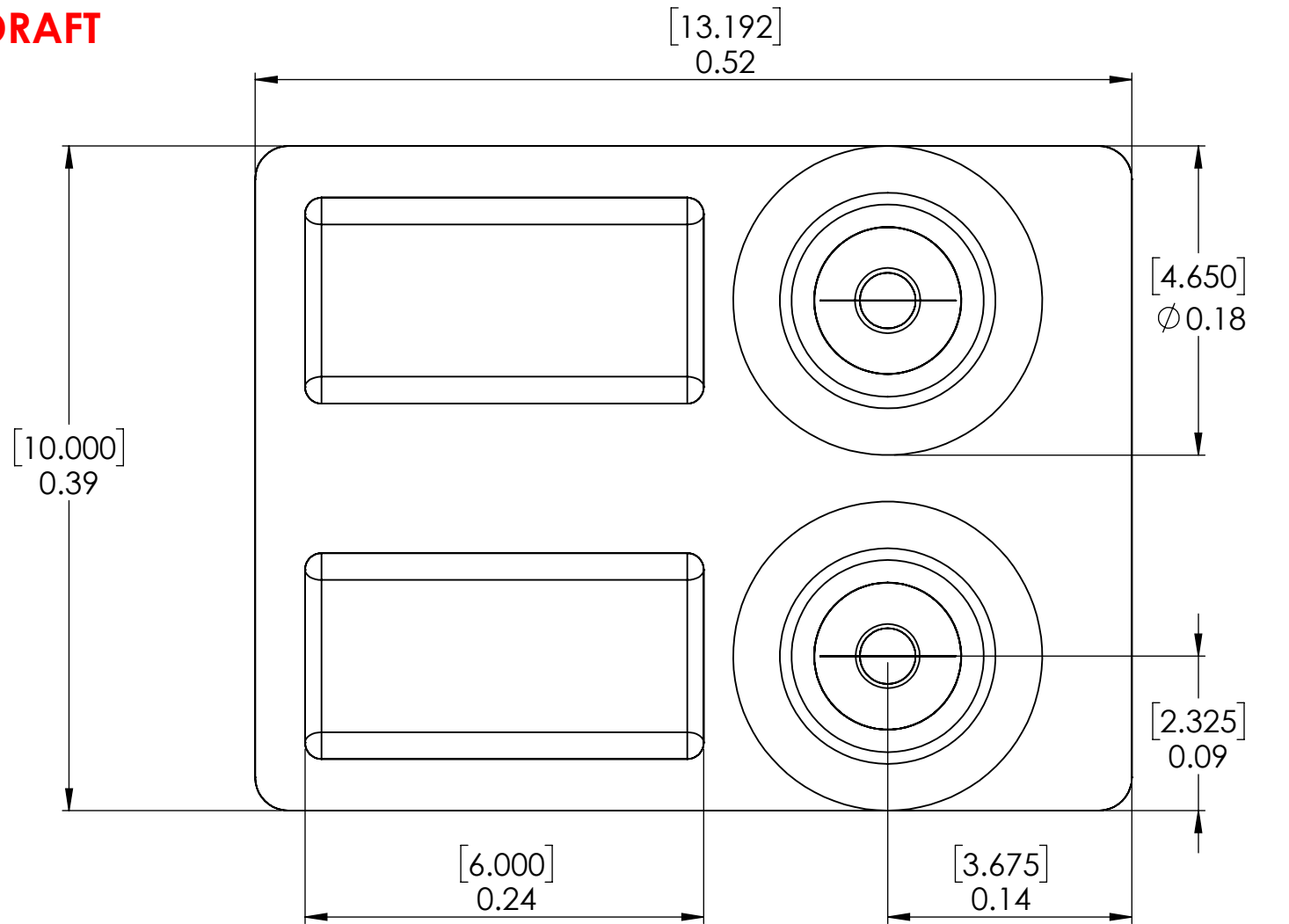
A

A

B

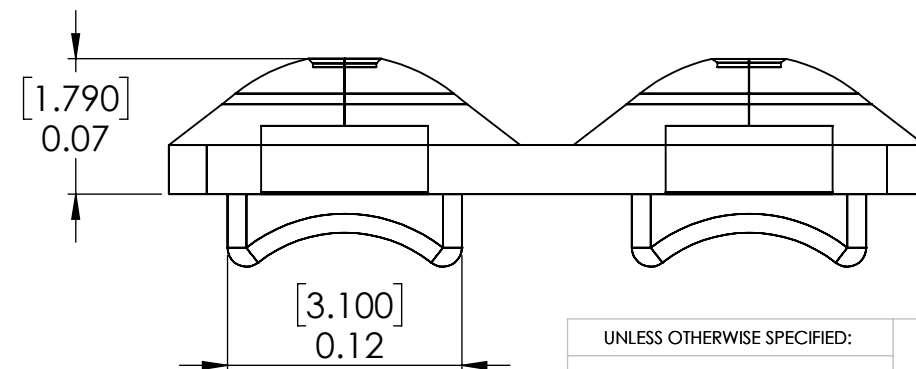
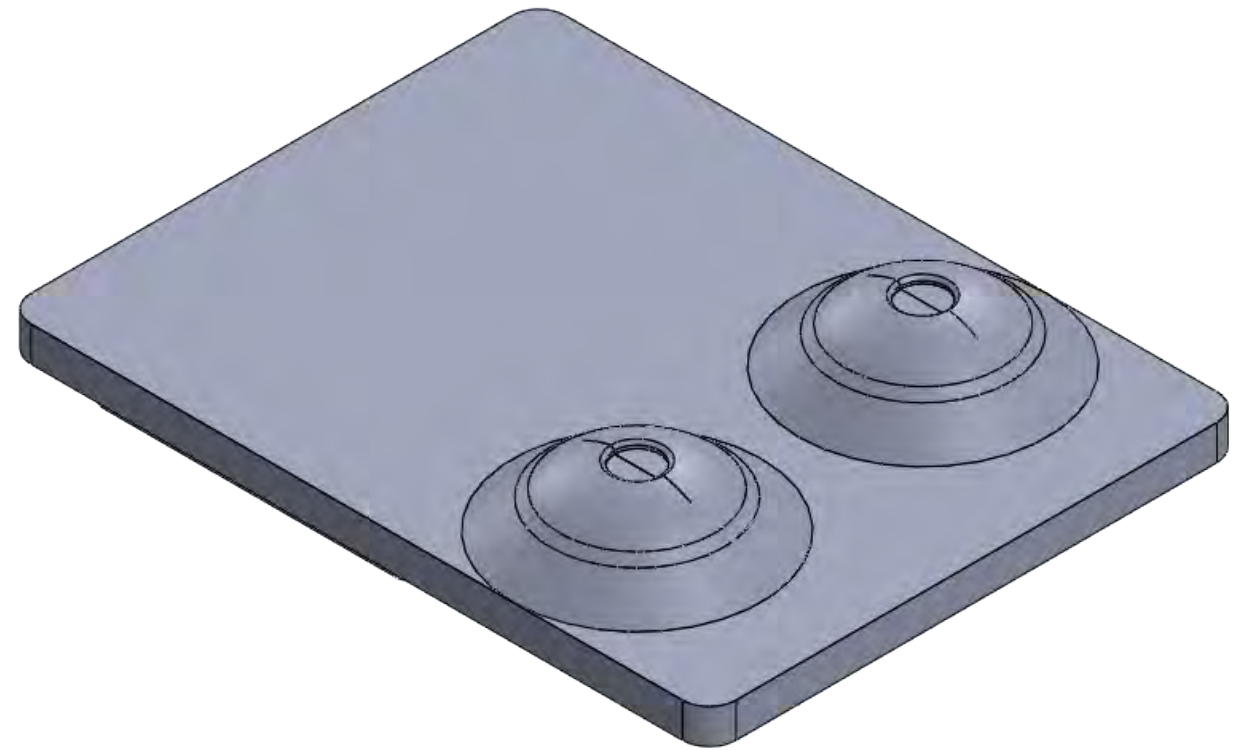
A

DRAFT



B


A



Model Number: 8277, Innerconnect Top Cover, Rev 1.0

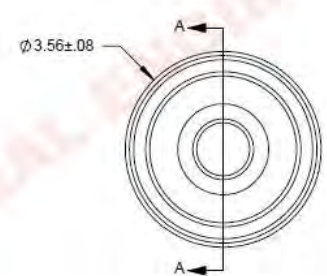
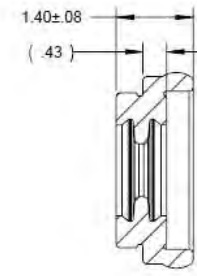
Next Assembly
3019

UNLESS OTHERWISE SPECIFIED:				
DIMENSIONS ARE IN [MM] / INCHES				
TOLERANCES:				
FRACTIONAL ±				
ANGULAR: MACH ±.5				
BEND ±				
TWO PLACE DECIMAL ±[0.20] / .008				
THREE PLACE DECIMAL ±[0.100] / .004				
DO NOT SCALE DRAWING				
PROPRIETARY AND CONFIDENTIAL				
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.				
MED-ALLY				
TITLE: Innerconnect Top Cover				
SIZE	DWG. NO.	REV		
B	6172	0.1		
SCALE: 10:1		SHEET 1 OF 1		

	Drawing No:	7002	Revision:	2.0
	Part No:	7002	Created By:	C. Mannarino
	Part Description 1:	BalSeal Seal		
	Part Description 2:	BalSeal Sygnus Neuro Seal		
Med-Ally, LLC 2040 Bushy Park Road, North Bldg 6 Goose Creek, SC 29445	Supplier Part No:	X605586 Rev B		
	Supplier Name:	BalSeal Engineering		
	Specification Control Drawing			

Rev	ECO Number	Description	Date
1.0	19-52	Initial release	12 Nov 19
2.0	19-14	Replace Newronika ICD with Med-Ally ICD.	23Mar2020

NOTES UNLESS OTHERWISE SPECIFIED		ECO#	DATE	APPROVED
<p>1. PROJECT INFORMATION ENGINEERING REQUEST: 22119 OPPORTUNITY: 21711 OPPORTUNITY DESCRIPTION: SYGNUS STANDARD NEUR</p> <p>2. CUSTOMER SUPPLIED APPLICATION DATA EQUIPMENT TYPE: MEDICAL ELECTRONICS</p> <p>3. THE CUSTOMER IS URGED TO READ RELEVANT BAL SEAL DOCUMENTS LOCATED AT WWW.BALSEAL.COM/TECHNICAL-LIBRARY</p> <p>4. UNCONTROLLED IF PRINTED. PLEASE CONTACT BAL SEAL ENGINEERING TO CONFIRM REVISION LEVEL.</p> <p>5. CERTIFICATE OF COMPLIANCE REQUIRED.</p>		61463	2019-03-18	J.KOMPA





SECTION A-A

PART DESCRIPTION		MATERIAL	
MEDICAL SEAL		IMPLANTABLE SILCONE RUBBER MED-4850	
UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN MILLIMETERS		CUSTOMER NAME MED-ALLY DRAWING NAME INTERFACE CONTROL DRAWING GAGE CODE DRAWING No. 09055 X605586 PROJ REPORT No. -	
TOLERANCES: DECIMALS: X = .05 X.X = ±.08 X.XX = ±.06 ANGULAR: X° = ±2° X' = ±10'	DRAWN J.KOMPA PROPOSED J.KOMPA ENG D. POON CHECK DILMASHANIAN SALES M. RUSSELL	DATE 2014-01-14 DATE 2014-01-14 DATE 2014-01-14 DATE 2014-01-14 DATE 2014-01-14	SCALE NONE PAGE No. 1 of 2 REV. B

Bal Seal Engineering, Inc. ("Bal Seal") has designed the Product described herein ("Product") in accordance with Customer provided data and requirements and as such Bal Seal cannot and does not warrant the Product for any particular intended purpose or use. Bal Seal recommends the Customer perform its own tests and determine for itself the performance characteristics of this Product to its own satisfaction. The Proposal and the information contained herein are subject to the Bal Seal Terms and Conditions of Sale attached hereto and made a part hereof. Any resulting purchase order should reference the noted Bal Seal Part Number, the attached Guide and these terms and conditions. Any other terms and conditions must be agreed to in writing by the parties hereto. Products are the subject of issued or pending United States and foreign patents. Products of Bal Seal and this Proposal are Proprietary and Products may not be manufactured, or caused to be manufactured, by any other party.

This document contains information PROPRIETARY to Bal Seal Engineering, Inc. and may not be used, reproduced, copied, published, distributed in any form, or disclosed to a third party, in whole or in part without the written authorization of an officer of Bal Seal Engineering, Inc. O-1996-ICDA REV A

	Drawing No:	7008	Revision:	1.0
	Part No:	7008	Created By:	C. Mannarino
	Part Description 1:	Epoxy, EPO-Tek 301		
	Part Description 2:	Epoxy Technology EPO-Tek 301		
Med-Ally,LLC 2040 Bushy Park Road, North Bldg 6 Goose Creek, SC 29445	Supplier Part No:	EPO-Tek 301		
	Supplier Name:	Epoxy Technology		
	Specification Control Drawing			

Rev	ECO Number	Description	Date
1.0	19-52	Initial release	12 Nov 19



EPO-TEK® 301

Technical Data Sheet
For Reference Only
Spectrally Transparent Epoxy

Date: September 2017
Rev: X
No. of Components: Two
Mix Ratio by Weight: 20 : 5
Specific Gravity: Part A: 1.15 Part B: 0.87
Pot Life: 1-2 Hours
Shelf Life- Bulk: One year at room temperature

Recommended Cure: 65°C / 2 Hours

Minimum Alternative Cure(s):
May not achieve performance properties listed below
85°C / 1 Hour
23°C / 24 Hours

NOTES:

- Container(s) should be kept closed when not in use.
- Filled systems should be stirred thoroughly before mixing and prior to use.
- Performance properties (rheology, conductivity, others) of the product may vary from those stated on the data sheet when bi-pak/syringe packaging or post-processing of any kind is performed. Epoxy's warranties shall not apply to any products that have been reprocessed or repackaged from Epoxy's delivered status/container into any other containers of any kind, including but not limited to syringes, bi-paks, cartridges, pouches, tubes, capsules, films or other packages.
- Syringe packaging will impact initial viscosity and effective pot life, potentially beyond stated parameters.
- TOTAL MASS SHOULD NOT EXCEED 25 GRAMS

Product Description: EPO-TEK® 301 is a two component, room temperature curing epoxy featuring very low viscosity, and excellent optical-mechanical properties.

Typical Properties: Cure condition: Varies as required. Different batches, conditions & applications yield differing results. Data below is not guaranteed. To be used as a guide only, not as a specification. * denotes test on lot acceptance basis

PHYSICAL PROPERTIES:			
* Color (before cure):	Part A: Clear/Colorless	Part B: Clear/Colorless	
* Consistency:	Pourable liquid		
* Viscosity (23°C) @ 100 rpm:	100 - 200	cPs	
Thixotropic Index:	N/A		
* Glass Transition Temp:	≥ 65	°C (Dynamic Cure: 20-200°C/ISO 25 Min; Ramp -10-200°C @20°C/Min)	
Coefficient of Thermal Expansion (CTE):			
Below Tg:	39	x 10 ⁻⁶ in/in°C	
Above Tg:	98	x 10 ⁻⁶ in/in°C	
Shore D Hardness:	85		
Lap Shear @ 23°C:	> 2,000	psi	
Die Shear @ 23°C:	≥ 10	Kg	3,556 psi
Degradation Temp:	430	°C	
Weight Loss:			
@ 200°C:	0.12	%	
@ 250°C:	0.13	%	
@ 300°C:	0.39	%	
Suggested Operating Temperature:	< 300	°C (Intermittent)	
Storage Modulus:	436,249	psi	
* Particle Size:	N/A		
ELECTRICAL AND THERMAL PROPERTIES:			
Thermal Conductivity:	N/A		
Volume Resistivity @ 23°C:	≥ 1 x 10 ¹³	Ohm-cm	
Dielectric Constant (1KHz):	4.00		
Dissipation Factor (1KHz):	0.016		
OPTICAL PROPERTIES @ 23°C:			
Spectral Transmission:	≥ 99% @ 382-980	nm	
	≥ 97% @ 980-1,640	nm	
	≥ 95% @ 1,640-2,040	nm	
Refractive Index:	1.519 @ 589	nm	

Epoxyes and Adhesives for Demanding Applications™

This information is based on data and tests believed to be accurate. Epoxy Technology, Inc. makes no warranties (expressed or implied) as to its accuracy and assumes no liability in connection with any use of this product.

EPOXY TECHNOLOGY, INC.
14 FORTUNE DRIVE, BILLERICA, MA 01821 (978) 667-3805, FAX (978) 663-9782
www.epotek.com

REVISIONS				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	21-40	INITIAL RELEASE	J. GETSINGER	22OCT2021
2.0		ADDED LENGTH TABLE AND WIRE QUANTITY NEEDED TO MAKE THE COILS	J. GETSINGER	13APR2023

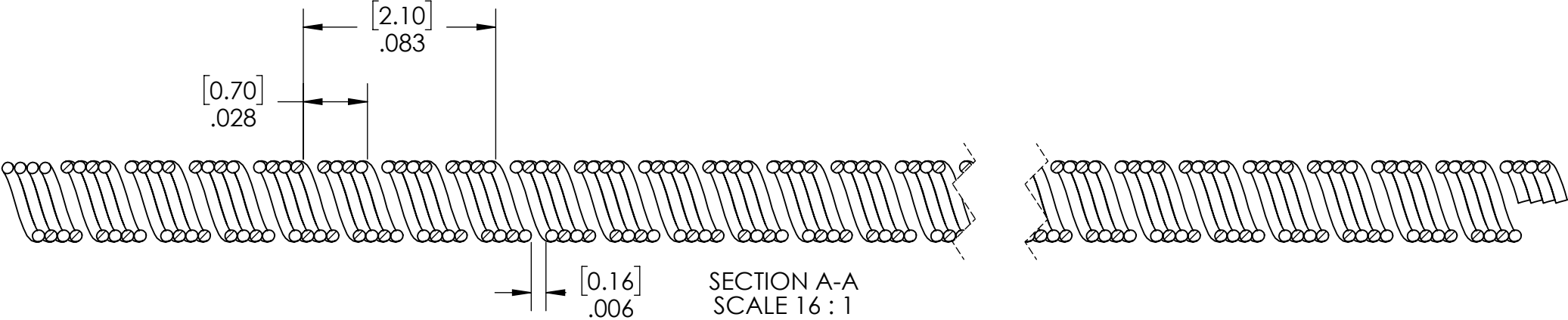
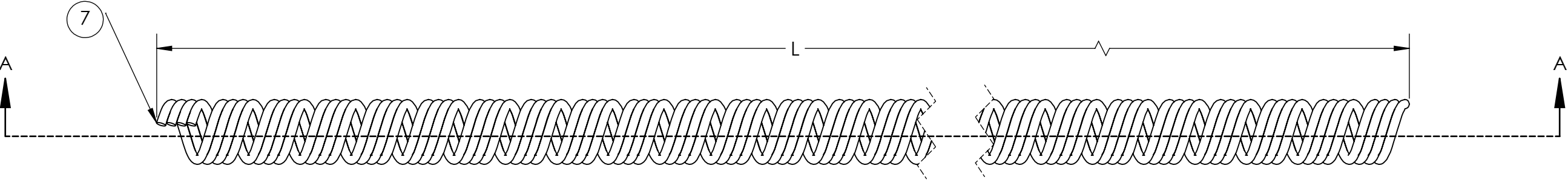



TABLE A		
PART NUMBER	LENGTH (MM)	REQUIRED PN 5014 TOTAL LENGTH (MM)[REF]
5019-350	350	4472
5019-400	400	5110
5019-500	500	6388

- NOTES:
- MATERIAL: PART NUMBER 5014 WIRE, COATED, 80% PT/20% IR
 - SEE TABLE A FOR DIFFERENT LENGTHS OF COILS (L) AND WIRE NEEDED TO MAKE THE COILS

NEXT ASSEMBLY
3009, 3011

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL \pm ANGULAR: MACH $\pm .5$ BEND \pm TWO PLACE DECIMAL $\pm [0.20]$ / .008 THREE PLACE DECIMAL $\pm [0.100]$ / .004 DO NOT SCALE DRAWING		TITLE: 4 FILAR COIL		
PROPRIETARY AND CONFIDENTIAL		SIZE B	DWG. NO. 5019	REV 2.0
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SCALE: 4:1		SHEET 1 OF 1

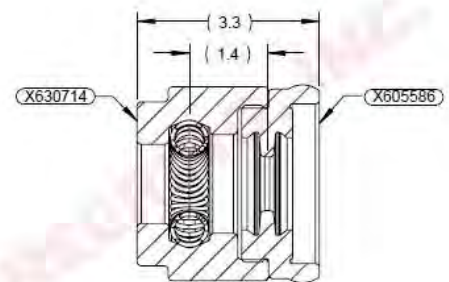
	Drawing No:	7001	Revision:	2.0
	Part No:	7001	Created By:	C. Mannarino
	Part Description 1:	BalSeal 2.8mm pitch contact		
	Part Description 2:	Balseal Sygnus Neuro 2.8mm Pitch Contact		
Med-Ally,LLC 2040 Bushy Park Road, North Bldg 6 Goose Creek, SC 29445	Supplier Part No:	X630714 Rev A		
	Supplier Name:	BalSeal Engineering		
	Specification Control Drawing			

Rev	ECO Number	Description	Date
1.0	19-52	Initial release	12 Nov 19
2.0	19-14	Replace Newronika ICD with Med-Ally ICD.	23Mar2020

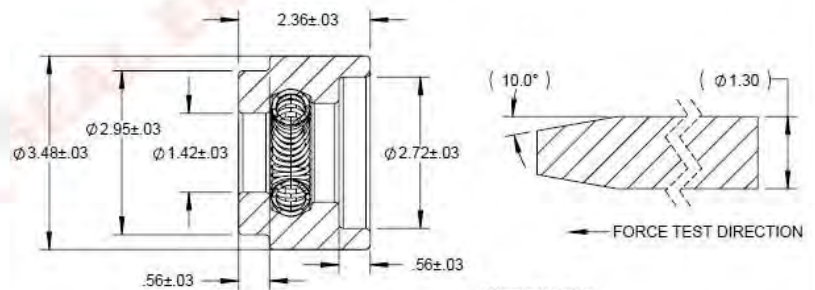
NOTES UNLESS OTHERWISE SPECIFIED

- PROJECT INFORMATION**
ENGINEERING REQUEST: 40958
OPPORTUNITY: 34517
OPPORTUNITY DESCRIPTION: MED-ALLY - UPDATED HOUSING DRAWINGS
- CUSTOMER SUPPLIED APPLICATION DATA**
EQUIPMENT TYPE: MEDICAL ELECTRONICS
- THE CUSTOMER IS URGED TO READ RELEVANT BAL SEAL DOCUMENTS LOCATED AT WWW.BALSEAL.COM/TECHNICAL-LIBRARY
- UNCONTROLLED IF PRINTED. PLEASE CONTACT BAL SEAL ENGINEERING TO CONFIRM REVISION LEVEL.
- CERTIFICATE OF COMPLIANCE REQUIRED.
- FORCE TEST INFORMATION:**
 - BREAKOUT FORCE MAX: 1.20 N
 - RUNNING FORCE RANGE: 0.09 - 0.40 N
- APPROXIMATE CONTACT PITCH: 2.8mm (NO AXIAL COMPRESSION)
FINAL PITCH CONTROLLED BY INTEGRATION.

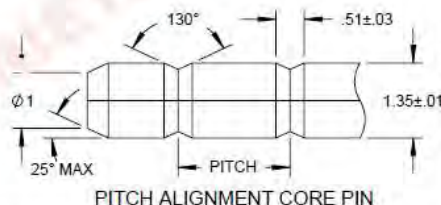
EO / ECO#	DATE	APPROVED
-	2020-03-10	J.KOMPA



SECTION MATE REFERENCE



SECTION VIEW



PITCH ALIGNMENT CORE PIN

Bal Seal Engineering, Inc. ("Bal Seal") has designed the Product described herein ("Product") in accordance with Customer provided data and requirements and as such Bal Seal cannot and does not warrant the Product for any particular intended purpose or use. Bal Seal recommends the Customer perform its own tests and determine for itself the performance characteristics of this Product to its own satisfaction. The Proposal and the information contained herein are subject to the Bal Seal Terms and Conditions of Sale attached hereto and made a part hereof. Any resulting purchase order should reference the noted Bal Seal Part Number, the attached Quote and these terms and conditions. Any other terms and conditions must be agreed to in writing by the parties hereto. Products are the subject of issued or pending United States and foreign patents. Products of Bal Seal and this Proposal are Proprietary and Products may not be manufactured, or caused to be manufactured, by any other party.

PART DESCRIPTION		MATERIAL	
101 DESIGN SPRING		PLATINUM IRIIDIUM 80/20	
MEDICAL HOUSING		MP35N® IAW ASTM F562	
(FORCE TEST PIN)		(HARDENED TOOL STEEL)	
(MEDICAL SEAL)		(MED-4850)	
UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN MILLIMETERS		DRAWN: J.KOMPA DATE: 2020-03-10	
TOLERANCES:		PROPOSED: J.KOMPA DATE: 2020-03-10	
DECIMALS: .X = ±.08 .XX = ±.03 .XXX = ±.01		ANGULAR: X° = ±2°	
THIRD ANGLE PROJECTION		BNG: E.FORT DATE: 2020-03-10	
		CHECK: M.BALTA DATE: 2020-03-10	
		SALES: O.PACCARELLI DATE: 2020-03-10	
		CUSTOMER NAME: MED-ALLY	
		DRAWING NAME: INTERFACE CONTROL DRAWING	
		CAGE CODE: 09055	
		DRAWING No: X630714	
		PROJ REPORT No: -	
		SIZE: A	
		PAGE No: 1 of 2	
		REV: A	
			
		Bal Seal Engineering, Inc. 19650 Pauling Foothill Ranch, CA 92610 Tel: (949) 460-2100 Fax: (949) 460-2300 Web: www.balseal.com	
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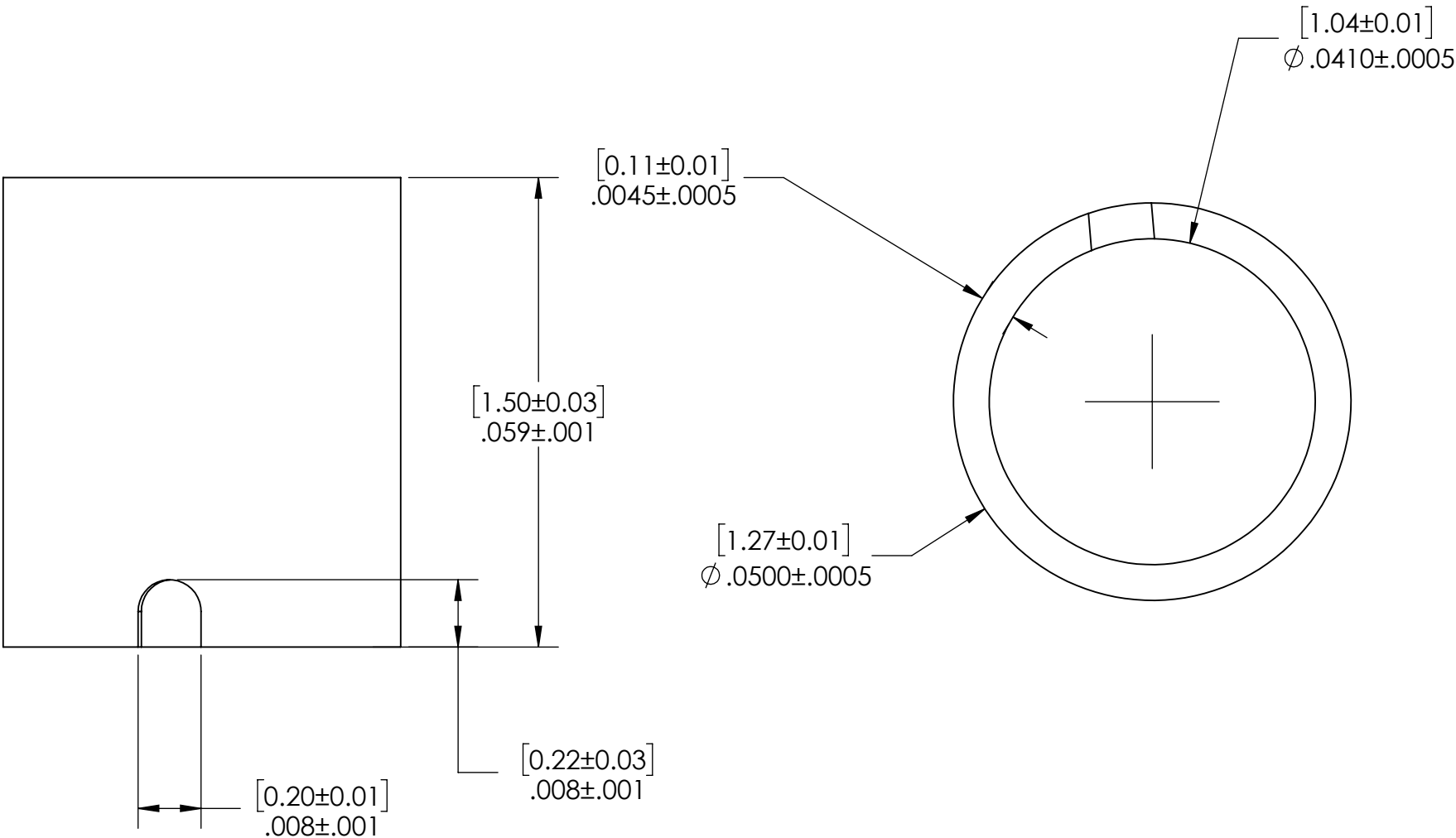
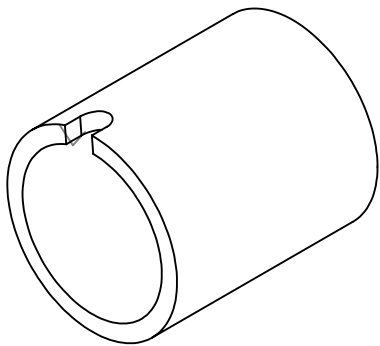
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1

REVISIONS				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	21-26	INITIAL RELEASE	J. GETSINGER	8/17/2021
2.0	21-37	RE-RELEASE	J. GETSINGER	10/13/2021



NOTES:

1. MATERIAL: MP35N
2. PARTS SHALL BE FREE OF BURRS AND SHARP EDGES

NEXT ASSEMBLY

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE: PROXIMAL CONTACT - 1.5MM		
		PROPRIETARY AND CONFIDENTIAL		
		THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		
		SIZE B	DWG. NO. 6090	REV 2.0
SCALE: 50:1		SHEET 1 OF 1		

4

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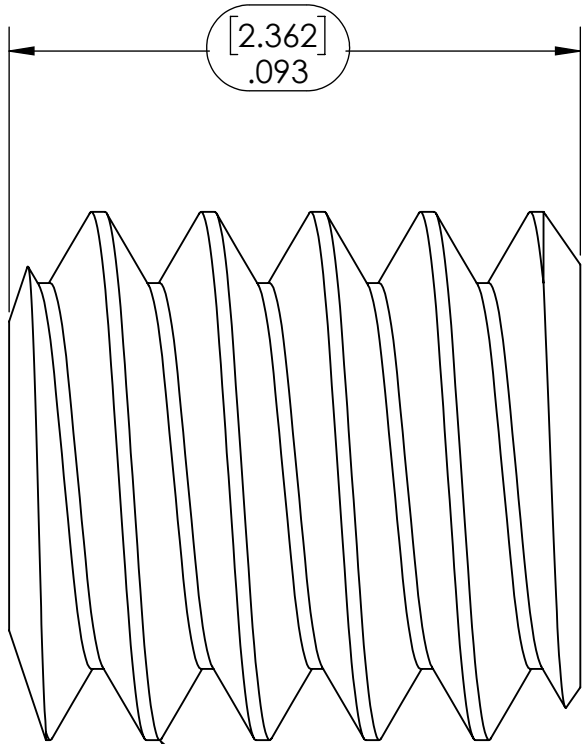
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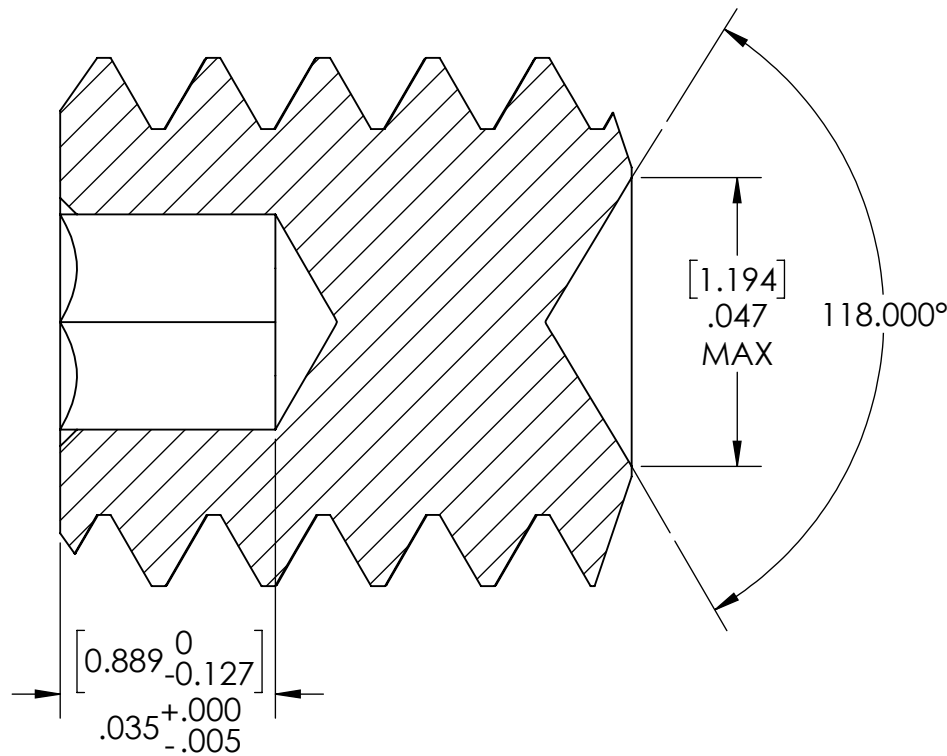
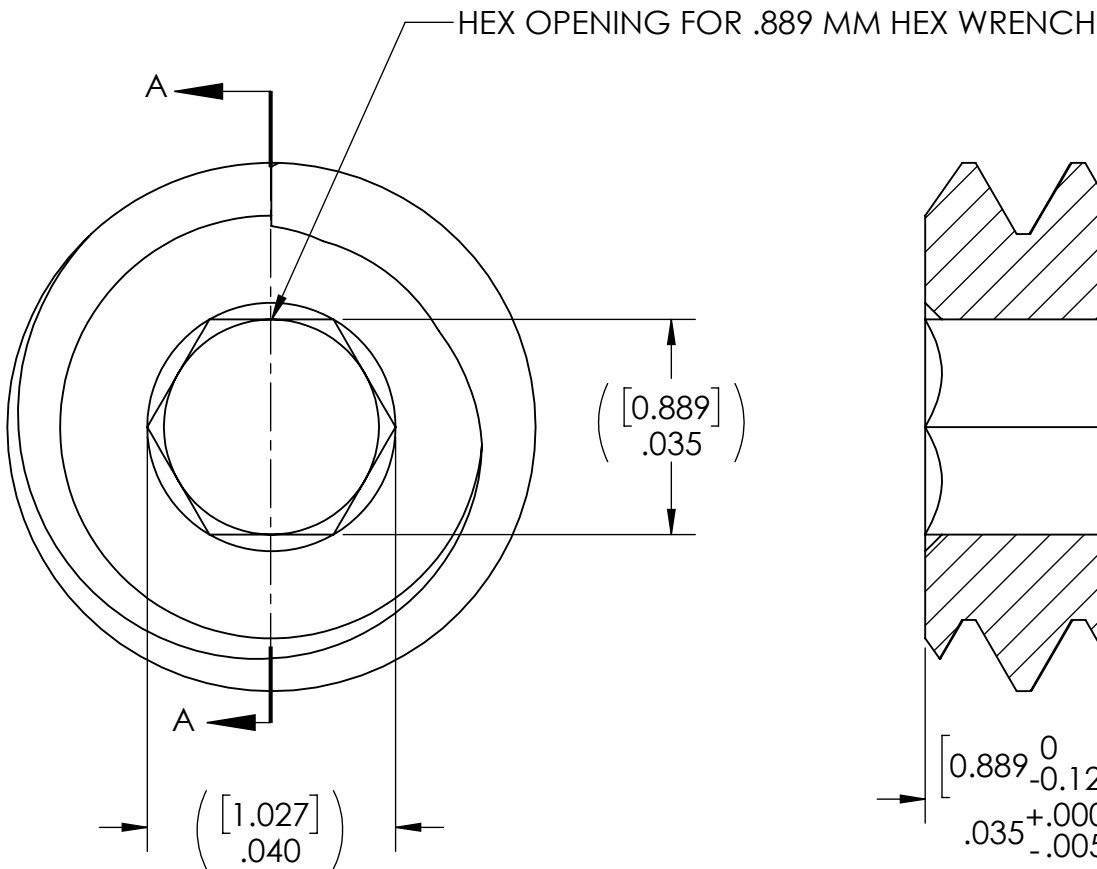
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1

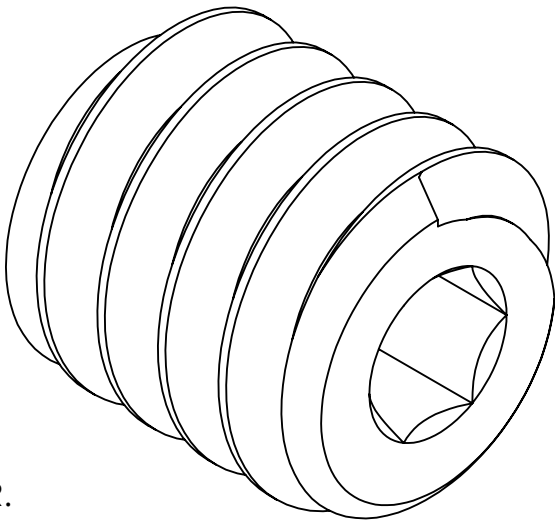
REVISIONS				
REV.	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	19-59	INITIAL RELEASE	S. BEHAN	11/26/19



#2-56 UNC-2B THREAD



SECTION A-A



NOTES:

1. MATERIAL: 316L STAINLESS STEEL.
2. PARTS ARE TO BE CLEAN AND FREE OF DIRT, GREASE AND OTHER PROCESS CONTAMINATES.
3. CRITICAL DIMENSIONS ON DRAWING ARE ENCLOSED IN OVALS. CRITICAL DIMENSIONS SHALL BE MEASURED AND RECORDED FOR EACH PART.
4. ALL MATERIALS USED TO MAKE THE PART SHALL BE TRACEABLE TO THE MATERIAL MANUFACTURER.
5. VENDOR SHALL SUPPLY INSPECTION SHEETS WITH DIMENSIONAL MEASUREMENTS OR TEST DOCUMENTATION TO ACCEPT THE SHIPPED PRODUCTION LOT, AND INCLUDE A COPY OF THE DRAWING USED FOR THE INSPECTION AND TEST.
6. SHIPPED PRODUCT SHALL BE PACKAGED TO PREVENT DAMAGE TO PARTS, AND LABELED WITH PART NUMBER, NAME AND SUPPLIERS WORK ORDER NUMBER(S) OR PRODUCTION LOT NUMBER(S) AND CONTAIN A CERTIFICATE OF CONFORMANCE.

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN MM TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±0.20 THREE PLACE DECIMAL ±0.10 DO NOT SCALE DRAWING PROPRIETARY AND CONFIDENTIAL THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		TITLE: #2-56 SETSCREW		
		SIZE B	DWG. NO. 6003	REV 1.0
		SCALE: 32:1		SHEET 1 OF 1

4

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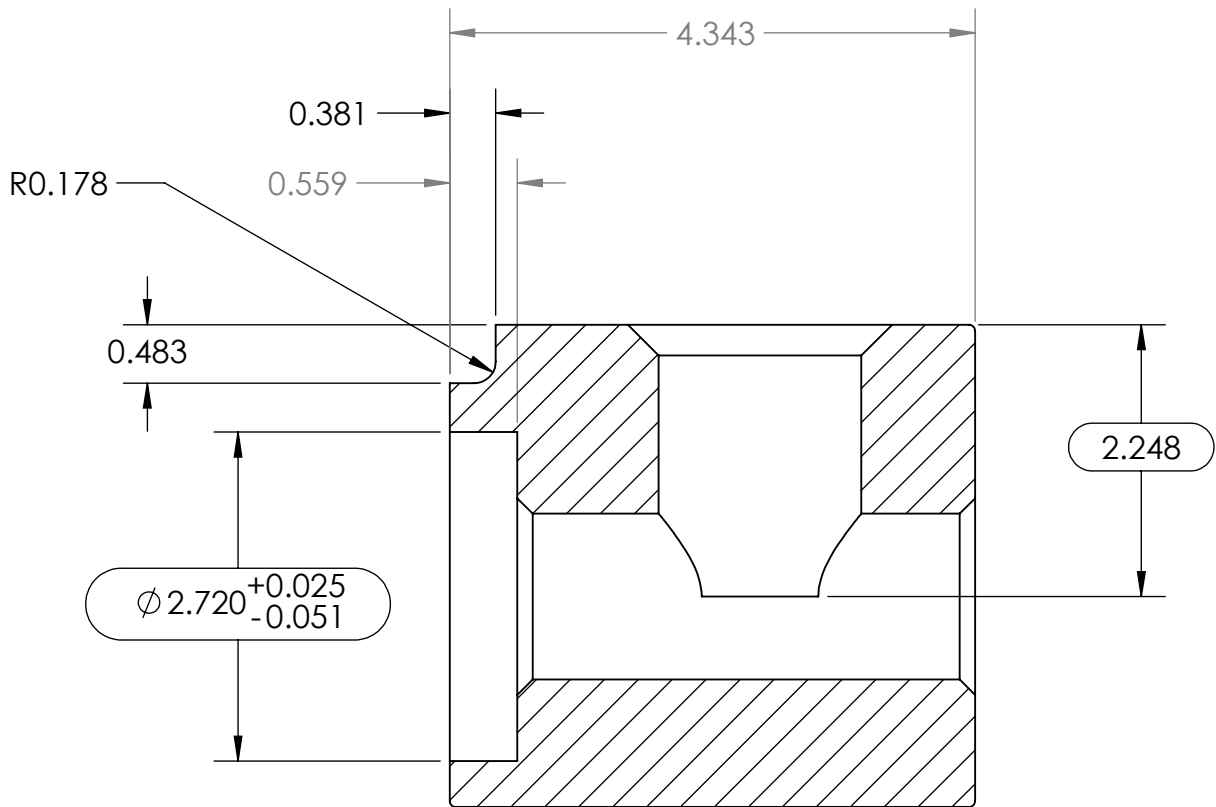
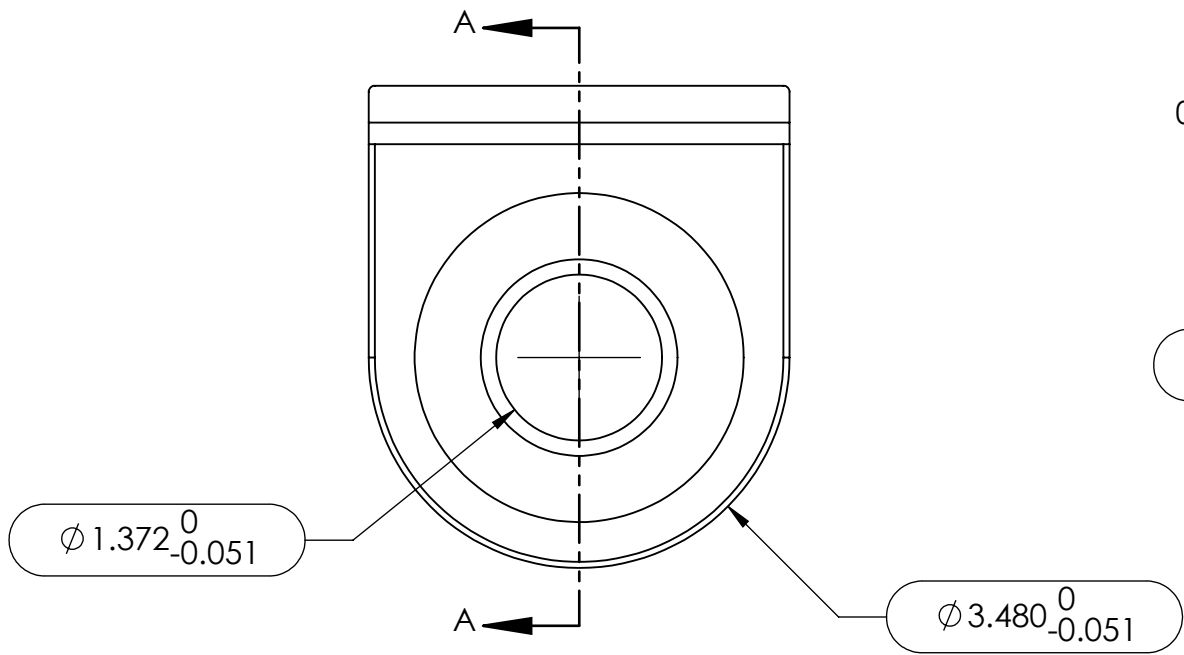
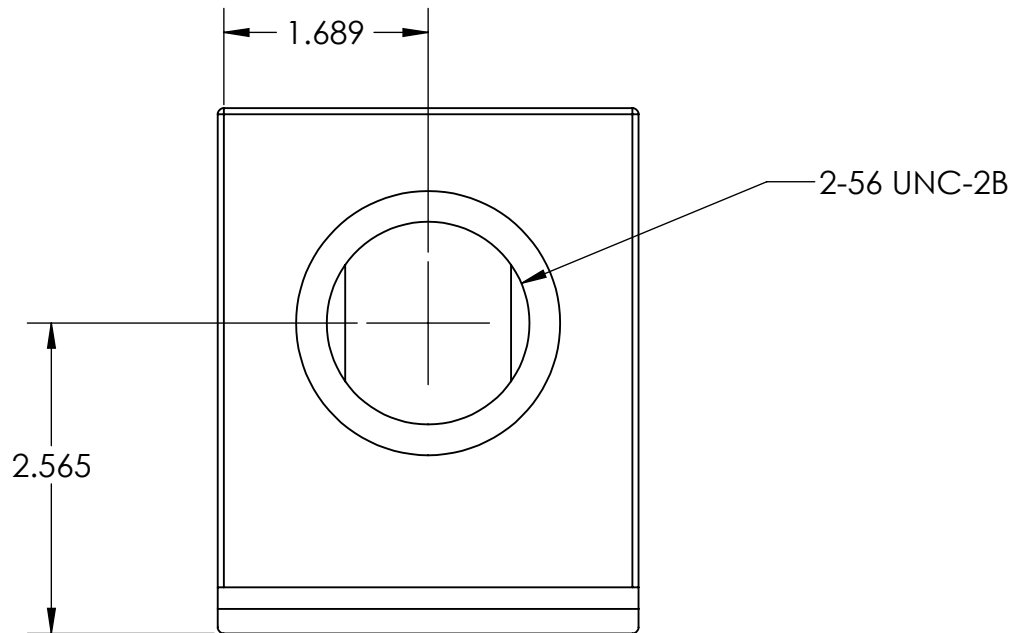
4

3

2

1

REVISIONS				
REV.	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	19-54	INITIAL RELEASE	S. BEHAN	11/19/19



SECTION A-A

- NOTES:
UNLESS OTHERWISE SPECIFIED:
1. MATERIAL: 316L STAINLESS STEEL.
 2. PARTS ARE TO BE CLEAN AND FREE OF DIRT, GREASE AND OTHER PROCESS CONTAMINATES.
 3. VENDOR SHALL SUPPLY MATERIAL CERTIFICATIONS WITH MATERIAL LOT NUMBERS USED IN FABRICATION OF PARTS / ASSEMBLIES.
 4. VENDOR SHALL SUPPLY INSPECTION SHEETS WITH DIMENSIONAL MEASUREMENTS OR TEST DOCUMENTATION TO ACCEPT THE SHIPPED PRODUCTION LOT, AND INCLUDE A COPY OF THE DRAWING USED FOR THE INSPECTION / TEST.

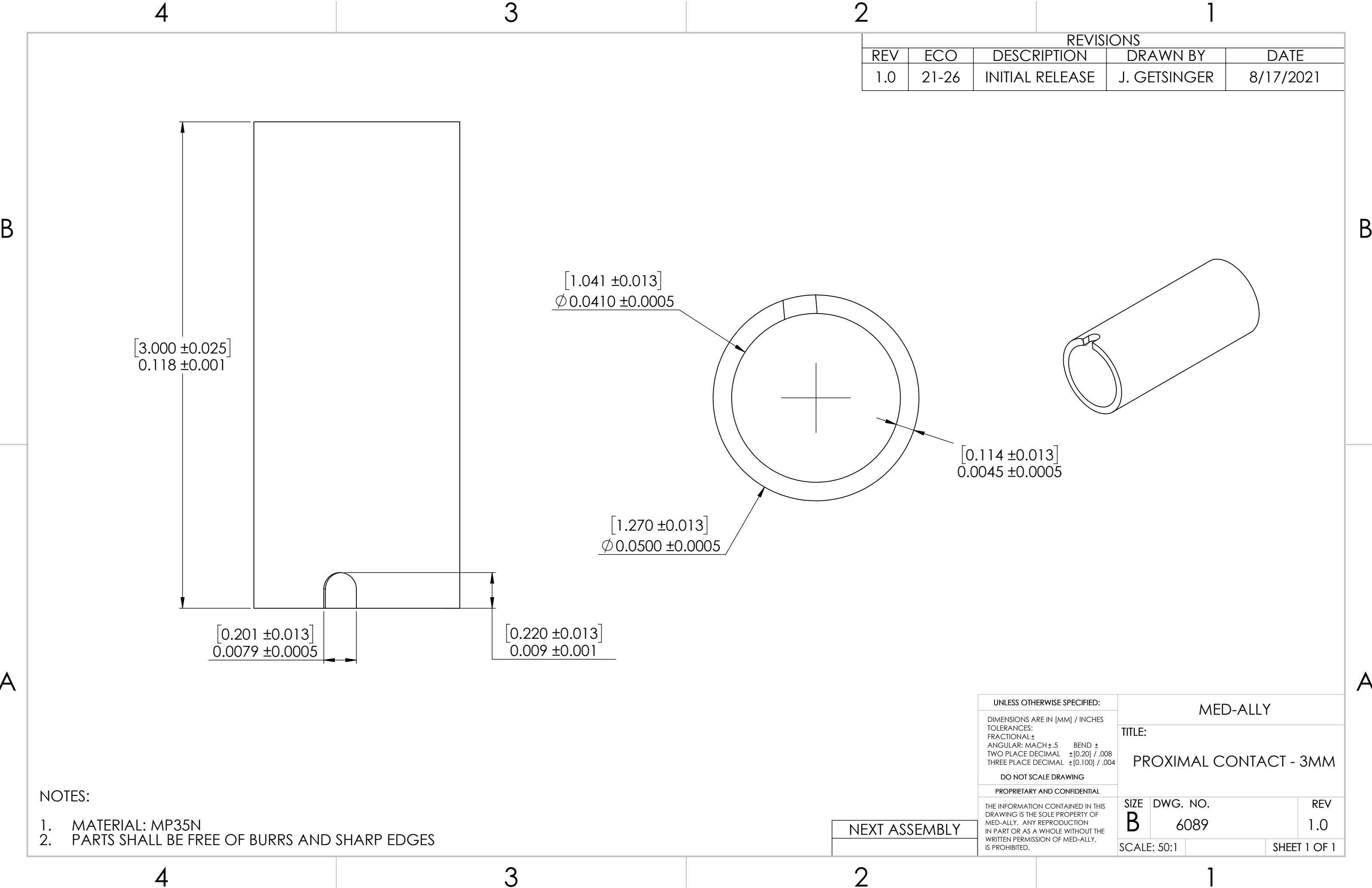
UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN MM TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±0.200 THREE PLACE DECIMAL ±0.100 DO NOT SCALE DRAWING PROPRIETARY AND CONFIDENTIAL THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		TITLE: CONNECTOR BLOCK	
		SIZE B	DWG. NO. 6005
		SCALE: 16:1	REV 1.0 SHEET 1 OF 1

4

3

2

1




REVISIONS				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	21-26	INITIAL RELEASE	J. GETSINGER	8/17/2021

- NOTES:
- MATERIAL: MP35N
 - PARTS SHALL BE FREE OF BURRS AND SHARP EDGES

NEXT ASSEMBLY

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE:		
		PROXIMAL CONTACT - 3MM		
		SIZE	DWG. NO.	REV
		B	6089	1.0
PROPRIETARY AND CONFIDENTIAL		SCALE: 50:1		
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SHEET 1 OF 1		

	Drawing No:	7065	Revision:	1.0
	Part No:	7065	Created By:	J. Getsinger
	Part Description 1:	Loctite M-11FL		
	Part Description 2:	Urethane Adhesive		
Med-Ally,LLC 2040 Bushy Park Road, North Bldg 6 Goose Creek, SC 29445	Supplier Part No:	235029		
	Supplier Name:	R.S. Hughes/Henkel		
	Specification Control Drawing			

Rev	ECO Number	Description	Date
1.0	ECO 22-28	Initial Release	4Nov22



Technical Information

Agency Approvals / Certificates / Specifications	ISO 10993
Cure Type	Room Temperature (Ambient) Cure
Key Characteristics	Flexible: Highly Flexible, Peel Strength: High, Peel Strength: Viscosity: Low Viscosity
Number of Components	2 Part
Physical Form	Liquid
Shear Strength, Aluminum (etched)	1850.0 psi
Shear Strength, Steel (grit blasted)	160.0 psi
Substrates	Glass, Metal, Plastic
Mixed	
Color, Mixed	Clear; Ultra Clear
Resin	
Color, Resin	Clear
Hardener	
Color, Hardener	Clear

B

B

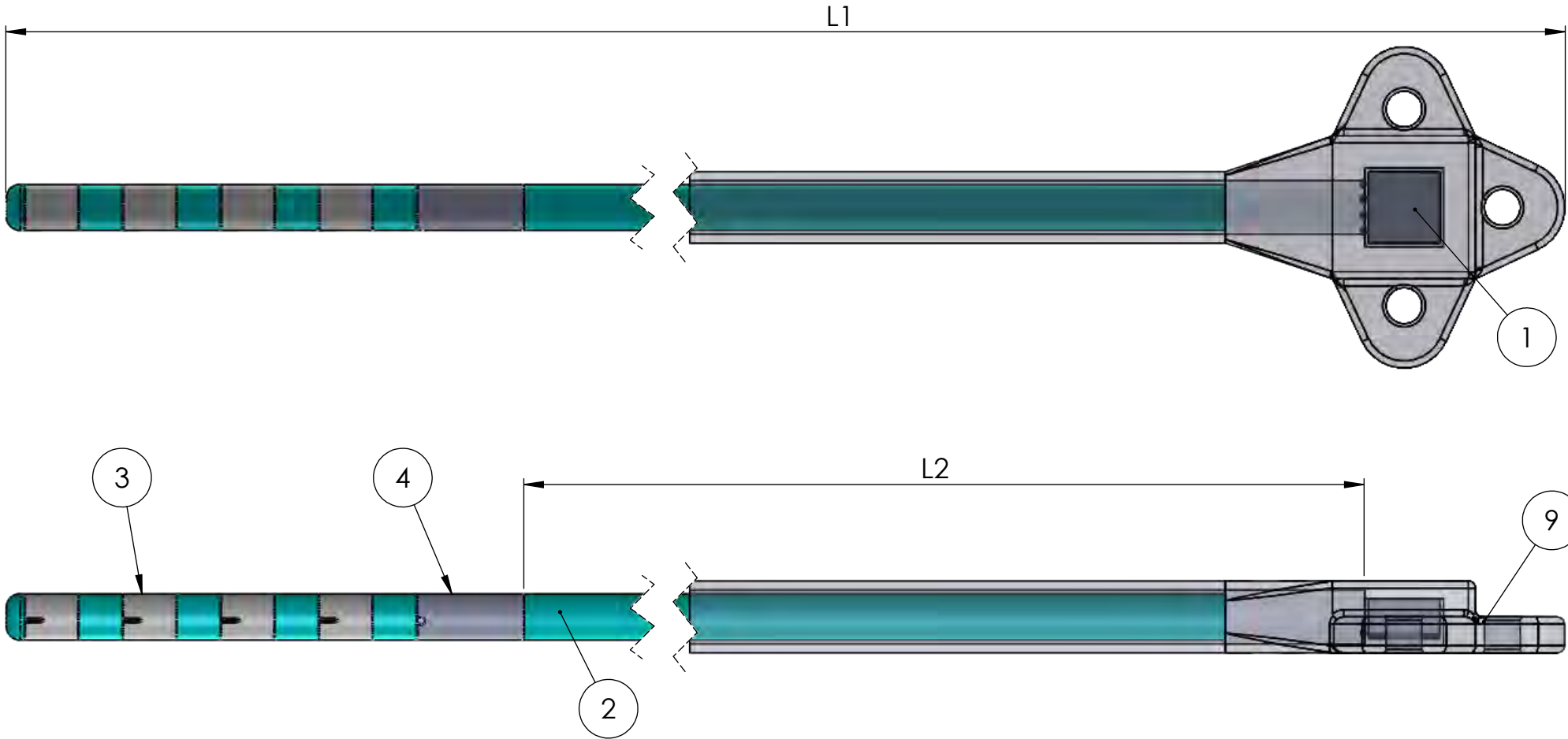
A

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DRAFT

REVISIONS

REV.	ECO	DESCRIPTION	DRAWN BY	DATE
0.1		Initial Release	F. Roberts	30 MAR 2023



ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	5037	Accelerometer	1
2	6085	Outer Tubing	L2
3	6090	Contact, Proximal, 1.50 mm	4
4	6089	Contact, Proximal, 3.00 mm	1
5	5019	4 Filar Coil	L1
6	6153	PEEK Single Lumen Tube	1
7	7065	Loctite M-11FL Urethane Adhesive	A/R
8	7073	Silicone Adhesive, MED-2000	A/R
9	6181	AMS Housing	1

Next Assembly

UNLESS OTHERWISE SPECIFIED:			
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING			
PROPRIETARY AND CONFIDENTIAL			
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.			
TITLE:		MED-ALLY	
		AMS Lead	
SIZE	DWG. NO.	REV	
B	3022	0.1	
SCALE: 5:1		SHEET 1 OF 5	

4

3

2

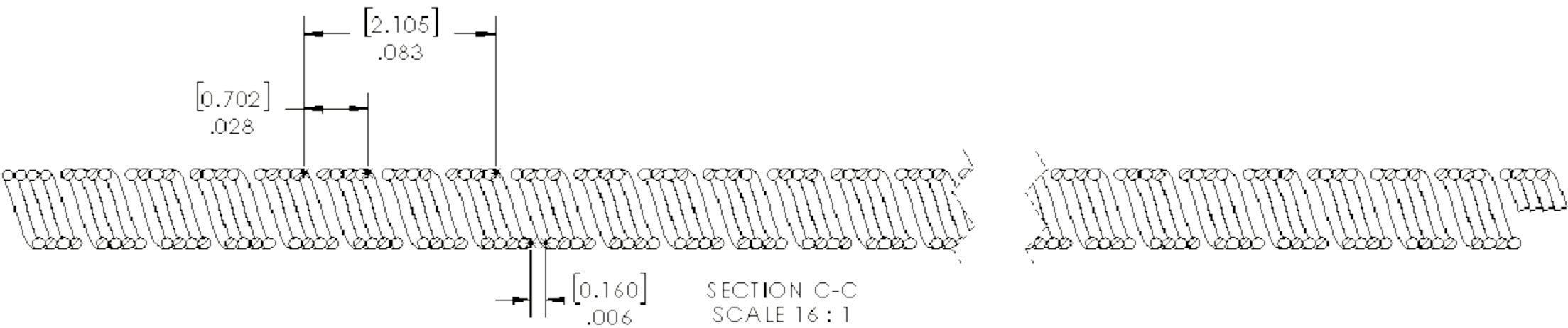
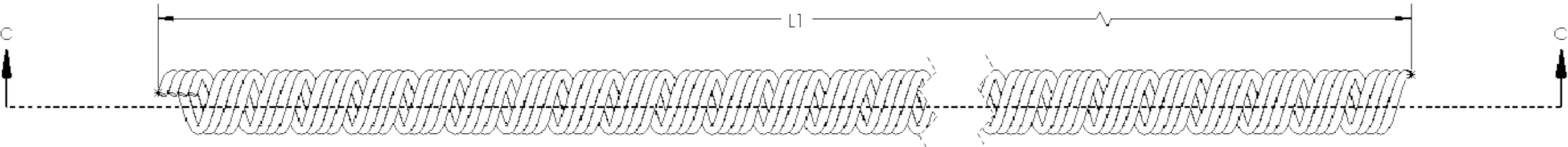
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DRAFT

Next Assembly

UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004		TITLE: AMS Lead	
DO NOT SCALE DRAWING			
PROPRIETARY AND CONFIDENTIAL			
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SIZE B	DWG. NO. 3022
		SCALE: 5:1	REV 0.1
		SHEET 2 OF 5	

4

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2

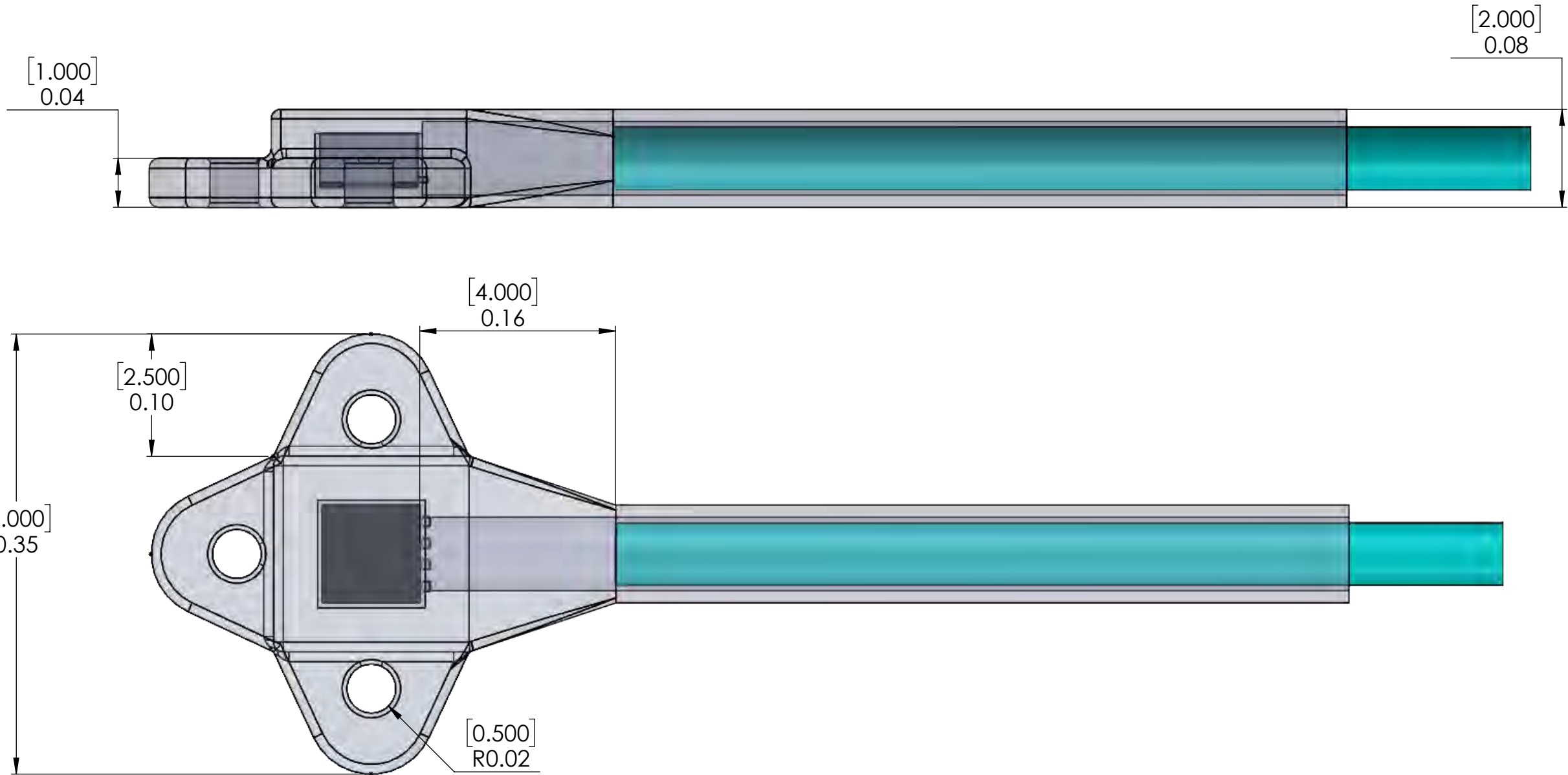
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DRAFT

Next Assembly

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES				
TOLERANCES:				
FRACTIONAL ±				
ANGULAR: MACH ±.5 BEND ±				
TWO PLACE DECIMAL ±[0.20] / .008		TITLE: AMS Lead		
THREE PLACE DECIMAL ±[0.100] / .004				
DO NOT SCALE DRAWING				
PROPRIETARY AND CONFIDENTIAL				
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SIZE	DWG. NO.	REV
		B	3022	0.1
		SCALE: 5:1		SHEET 3 OF 5

4

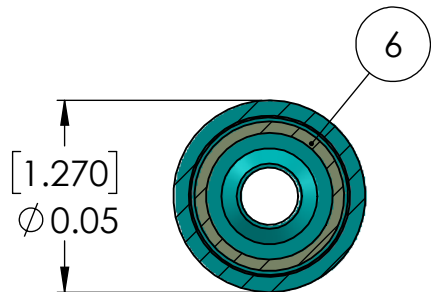
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2

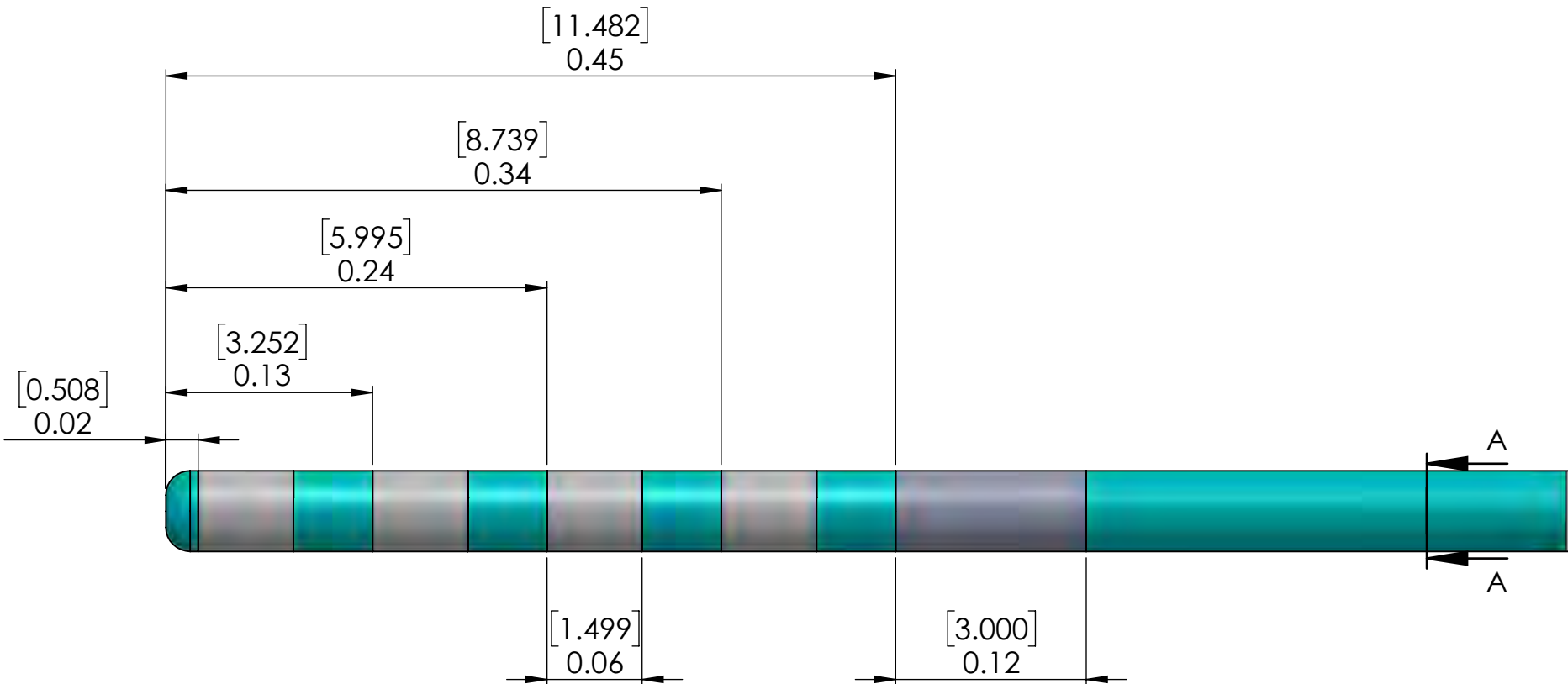
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B

B



SECTION A-A
SCALE 20 : 1



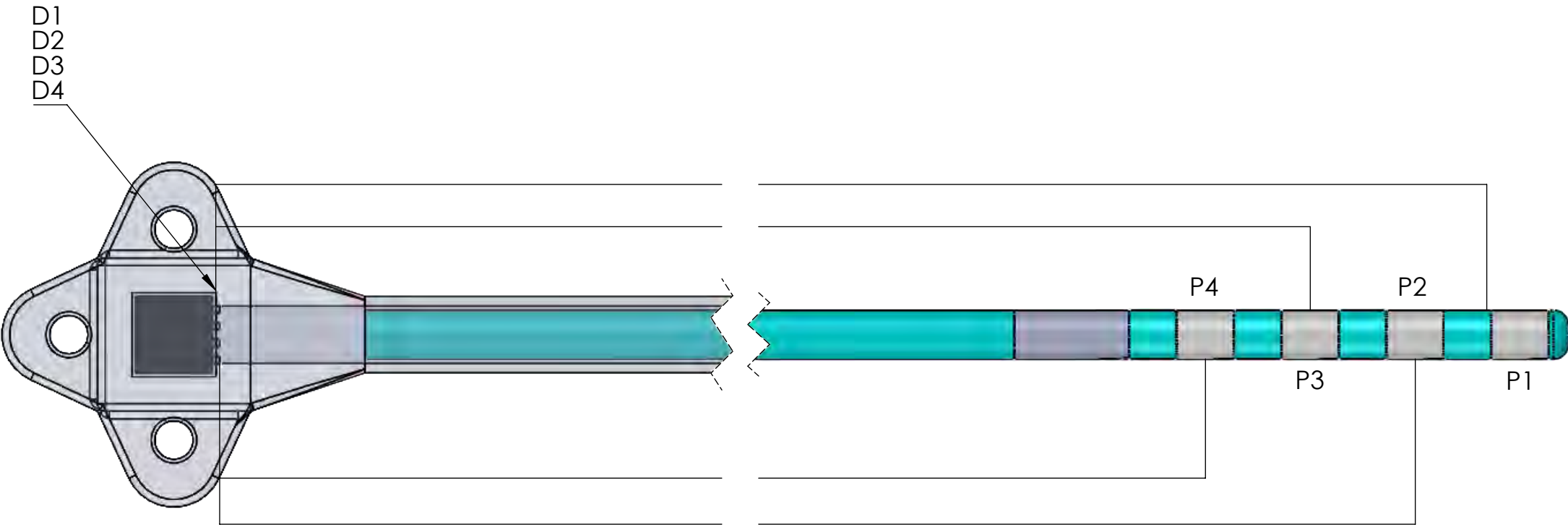
DRAFT

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Next Assembly

UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE: AMS Lead	
PROPRIETARY AND CONFIDENTIAL			
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SIZE B	DWG. NO. 3022 REV 0.1
		SCALE: 5:1	SHEET 4 OF 5



DRAFT

Next Assembly

UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING			
PROPRIETARY AND CONFIDENTIAL		TITLE: AMS Lead	
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.			
SIZE B	DWG. NO. 3022	REV 0.1	
SCALE: 5:1		SHEET 5 OF 5	

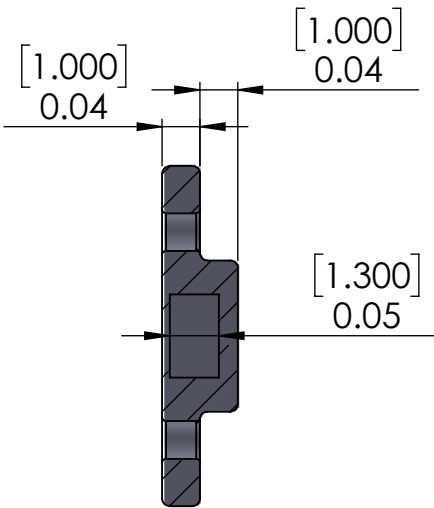
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3

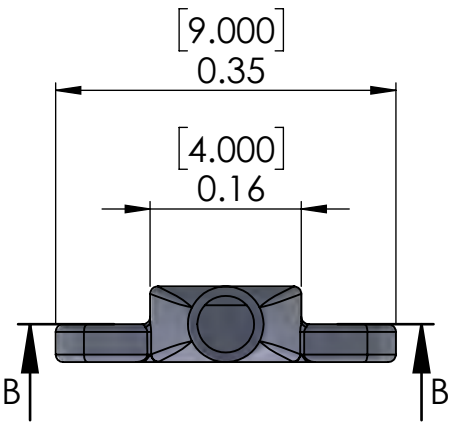
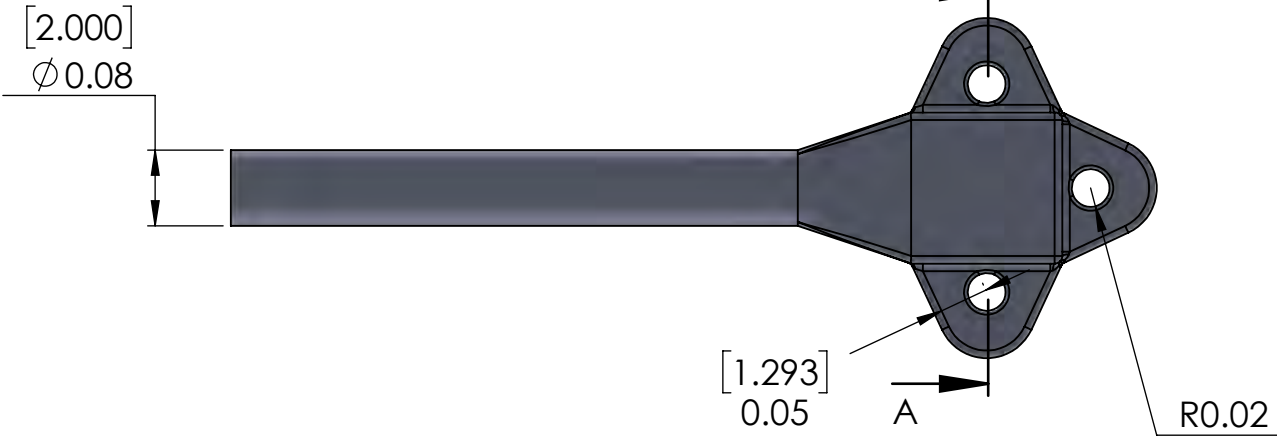
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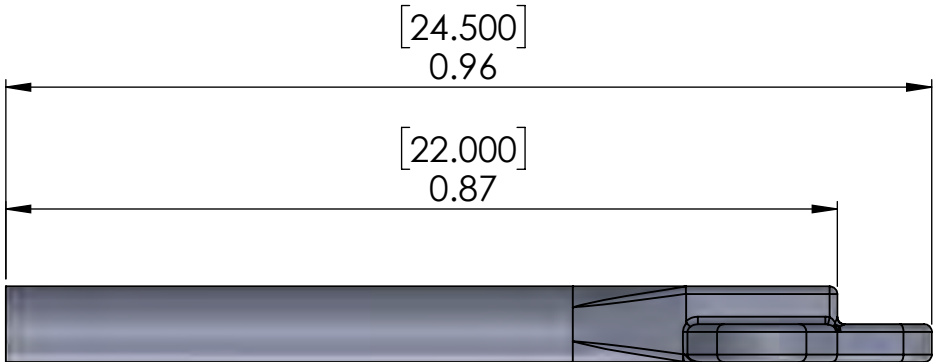
REVISIONS				
REV.	ECO	DESCRIPTION	DRAWN BY	DATE
0.1		INITIAL RELEASE	F.ROBERTS	2 JUN 2023



SECTION A-A



SECTION B-B

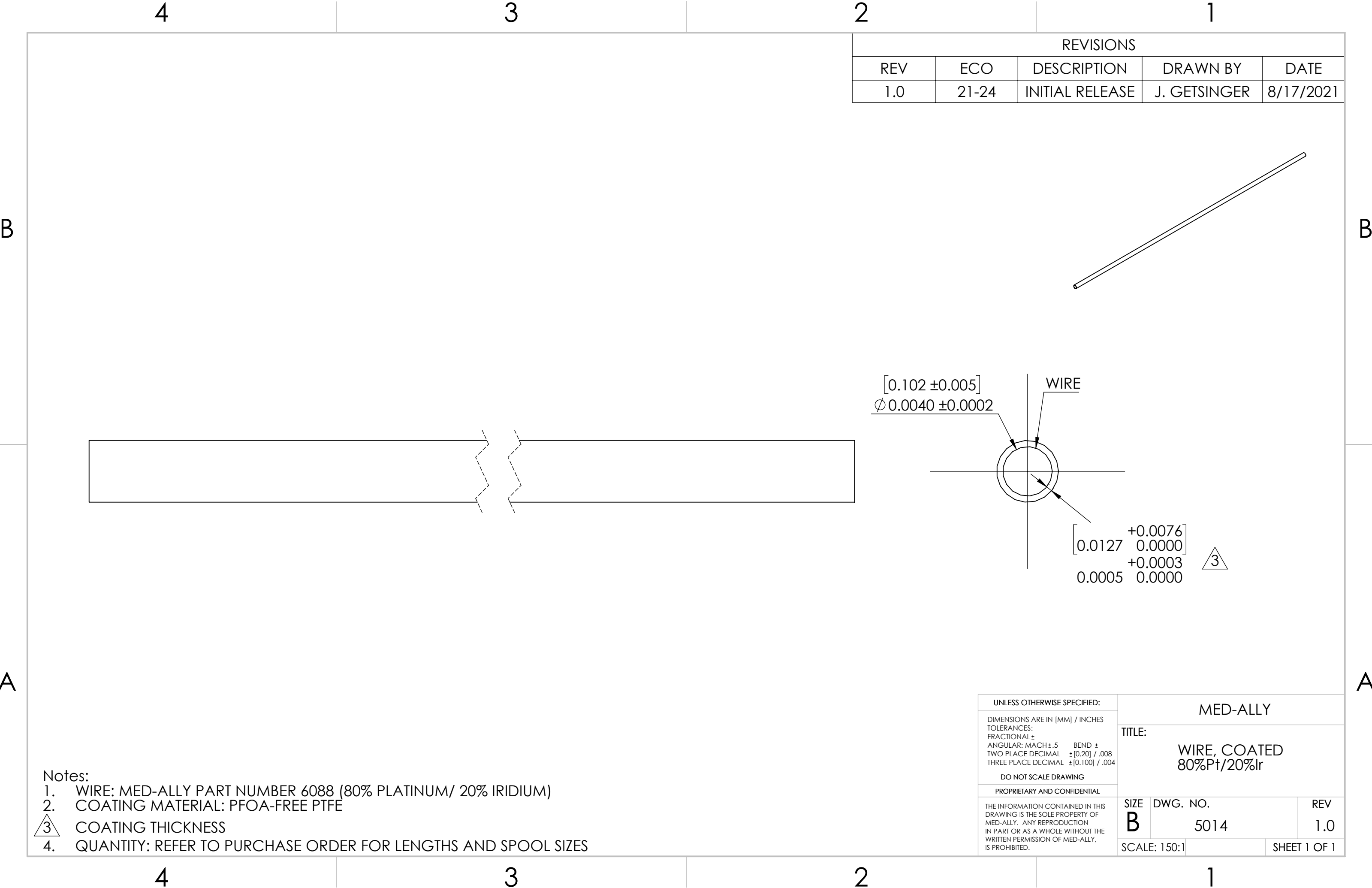


DRAFT

NOTES:
1. MATERIAL: IMPLANT GRADE SILICONE - NUSIL MED 4840

Next Assembly
3022

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING PROPRIETARY AND CONFIDENTIAL THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		TITLE:		
		AMS Housing		
		SIZE B	DWG. NO. 6181	REV 0.1
		SCALE: 5:1		SHEET 1 OF 1

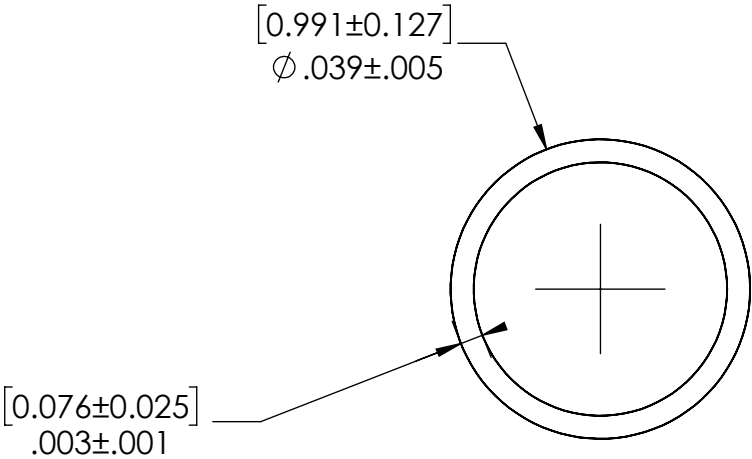
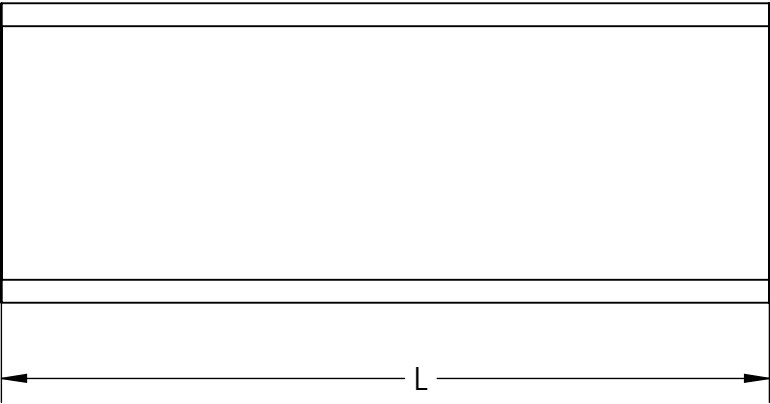
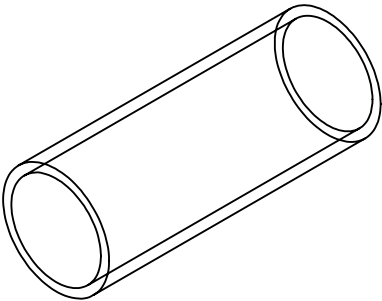


REVISIONS				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	21-24	INITIAL RELEASE	J. GETSINGER	8/17/2021

- Notes:
1. WIRE: MED-ALLY PART NUMBER 6088 (80% PLATINUM/ 20% IRIIDIUM)
 2. COATING MATERIAL: PFOA-FREE PTFE
 3. COATING THICKNESS
 4. QUANTITY: REFER TO PURCHASE ORDER FOR LENGTHS AND SPOOL SIZES

UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE: WIRE, COATED 80%Pt/20%Ir	
PROPRIETARY AND CONFIDENTIAL		SIZE B	DWG. NO. 5014
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		REV 1.0	SCALE: 150:1
		SHEET 1 OF 1	

Revisions				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	22-28	INITIAL RELEASE	J. GETSINGER	4NOV22



- NOTES:
1. MATERIAL: PEEK
 2. LENGTH (L) WILL BE DISTINGUISHED ON PO

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE: PEEK SINGLE LUMEN TUBE		
		PROPRIETARY AND CONFIDENTIAL		
		THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		
		SIZE B	DWG. NO. 6153	REV 1.0
SCALE: 40:1		SHEET 1 OF 1		

4

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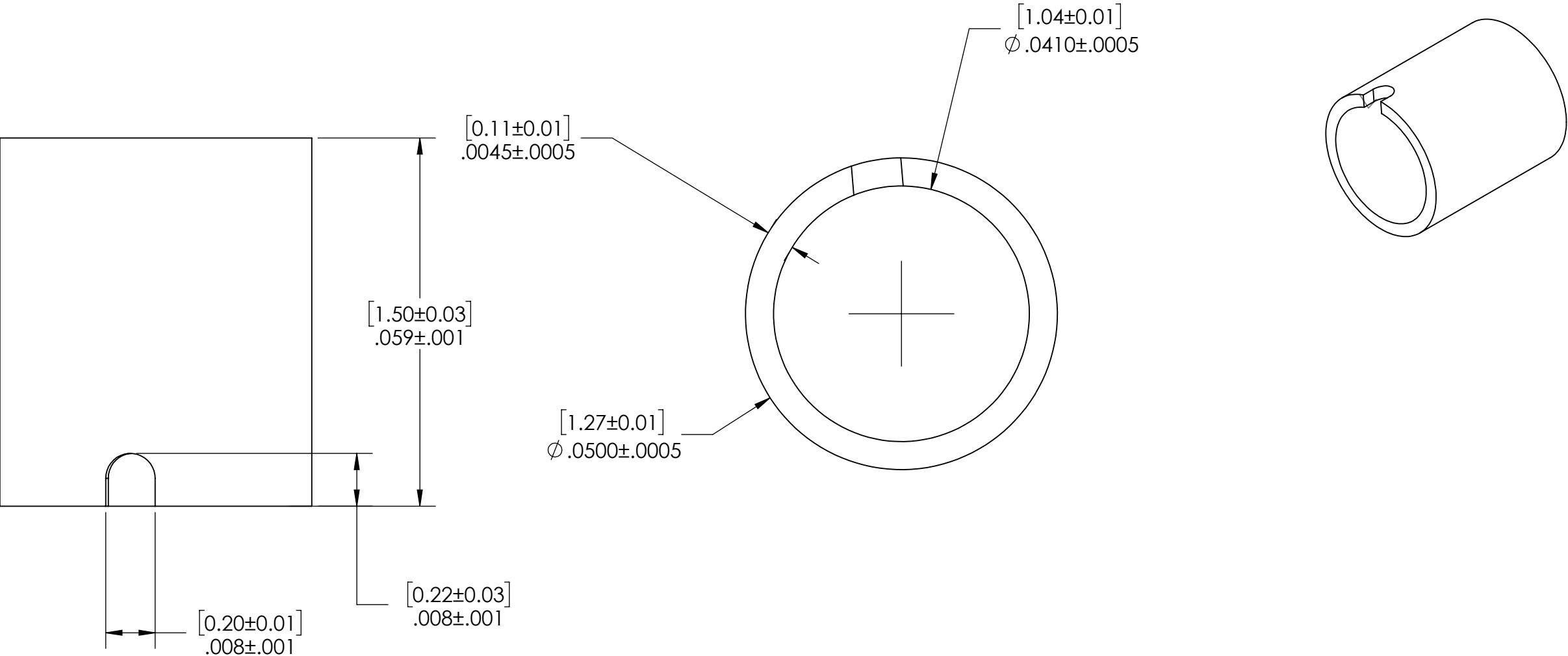
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1

REVISIONS				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	21-26	INITIAL RELEASE	J. GETSINGER	8/17/2021
2.0	21-37	RE-RELEASE	J. GETSINGER	10/13/2021

B

B



A

A

- NOTES:
1. MATERIAL: MP35N
 2. PARTS SHALL BE FREE OF BURRS AND SHARP EDGES

NEXT ASSEMBLY

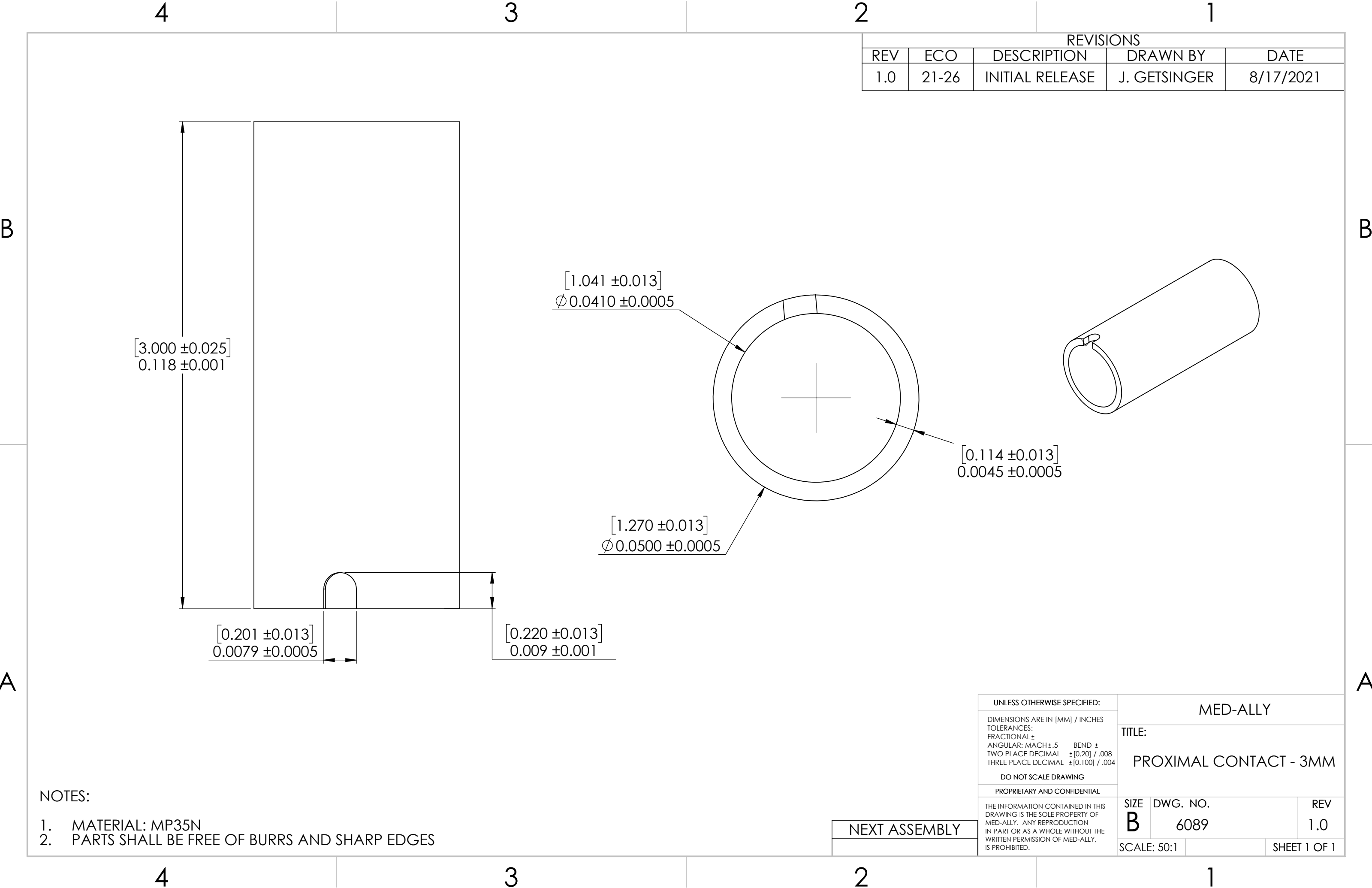
UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE: PROXIMAL CONTACT - 1.5MM		
		PROPRIETARY AND CONFIDENTIAL		
		THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		
		SIZE B	DWG. NO. 6090	REV 2.0
SCALE: 50:1		SHEET 1 OF 1		

4

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REVISIONS				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	21-26	INITIAL RELEASE	J. GETSINGER	8/17/2021

- NOTES:
- MATERIAL: MP35N
 - PARTS SHALL BE FREE OF BURRS AND SHARP EDGES

NEXT ASSEMBLY

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING		TITLE:		
		PROXIMAL CONTACT - 3MM		
		SIZE	DWG. NO.	REV
		B	6089	1.0
PROPRIETARY AND CONFIDENTIAL		SCALE: 50:1		
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		SHEET 1 OF 1		

REVISIONS				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	21-40	INITIAL RELEASE	J. GETSINGER	22OCT2021
2.0		ADDED LENGTH TABLE AND WIRE QUANTITY NEEDED TO MAKE THE COILS	J. GETSINGER	13APR2023

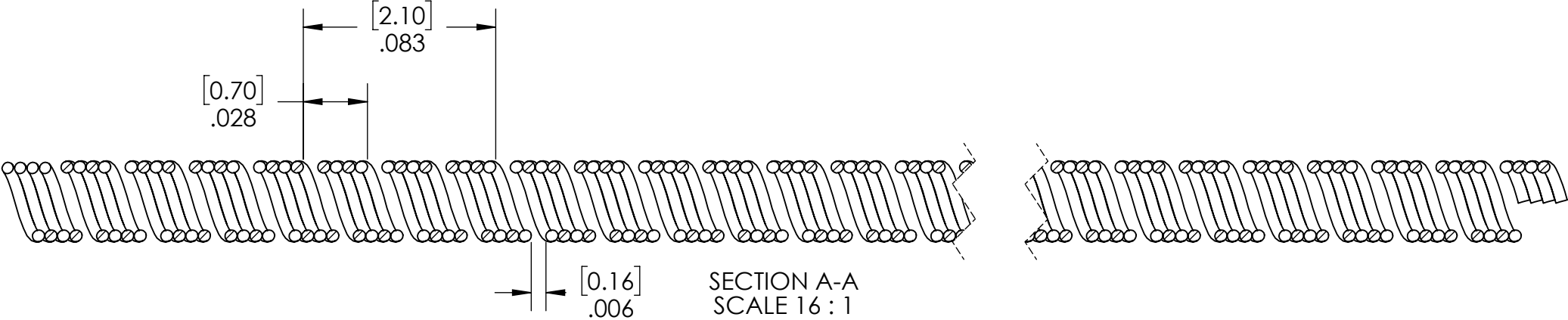
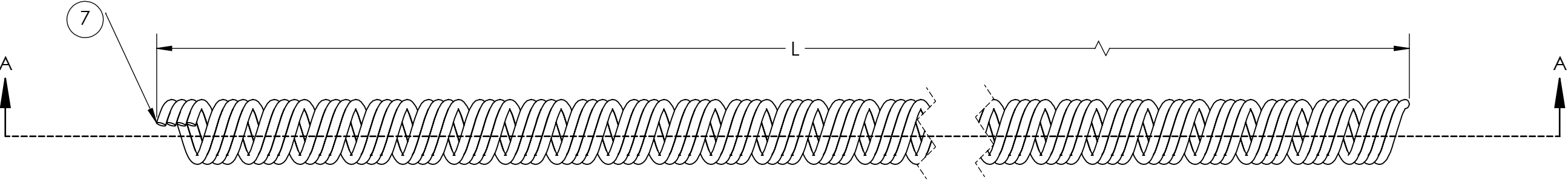


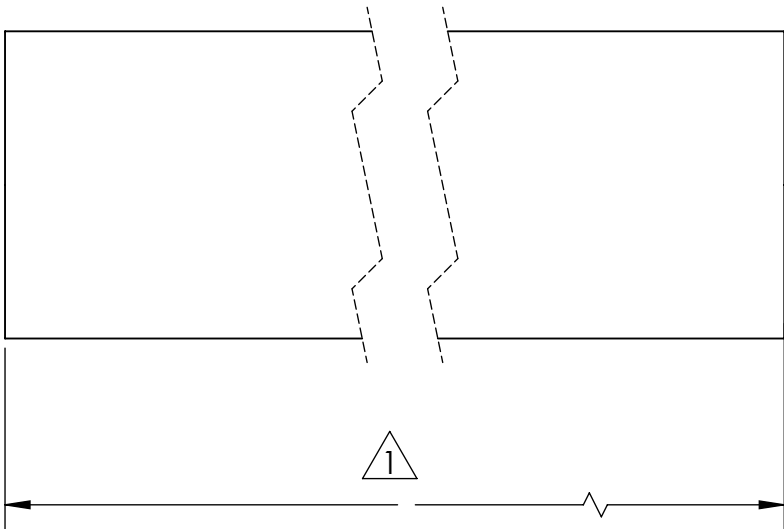
TABLE A		
PART NUMBER	LENGTH (MM)	REQUIRED PN 5014 TOTAL LENGTH (MM)[REF]
5019-350	350	4472
5019-400	400	5110
5019-500	500	6388

- NOTES:
- MATERIAL: PART NUMBER 5014 WIRE, COATED, 80% PT/20% IR
 - SEE TABLE A FOR DIFFERENT LENGTHS OF COILS (L) AND WIRE NEEDED TO MAKE THE COILS

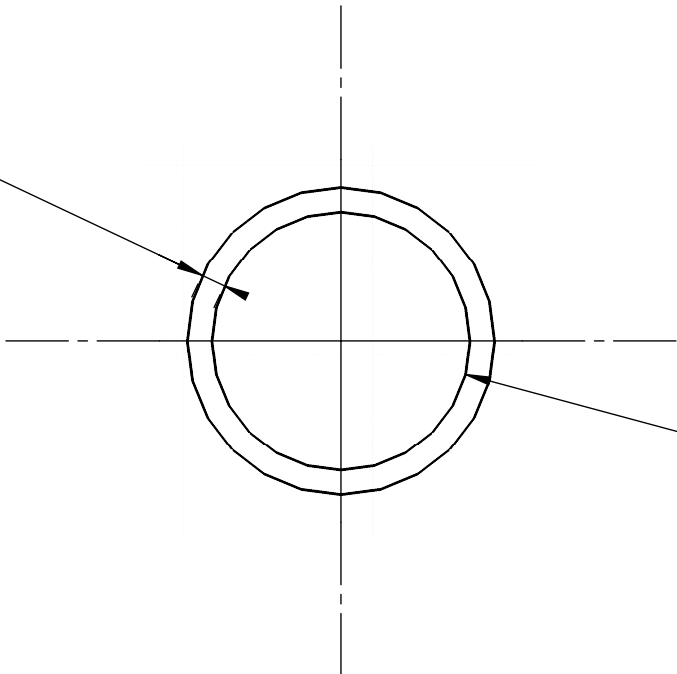
NEXT ASSEMBLY
3009, 3011

UNLESS OTHERWISE SPECIFIED:		MED-ALLY		
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL \pm ANGULAR: MACH \pm .5 BEND \pm TWO PLACE DECIMAL \pm [0.20] / .008 THREE PLACE DECIMAL \pm [0.100] / .004 DO NOT SCALE DRAWING PROPRIETARY AND CONFIDENTIAL THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		TITLE:		
		4 FILAR COIL		
		SIZE B	DWG. NO. 5019	REV 2.0
		SCALE: 4:1		SHEET 1 OF 1

REVISIONS				
REV	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	21-24	INITIAL RELEASE	J. GETSINGER	12AUG21
2.0	21-45	REMOVED MATERIAL FROM NAME, CHANGED ID FROM 0.039 TO 0.042 AND DIMENSIONED WALL INSTEAD OF OD	J.GETSINGER	6DEC21




[0.10±0.04]
.0040±.0015



[1.07±0.04]
Ø.0420±.0015

- NOTES:
- 1 REFER TO TUBING LENGTH SPECIFIED ON PURCHASE ORDER
 2. MATERIAL: POLYURETHANE, 55D

UNLESS OTHERWISE SPECIFIED:		MED-ALLY	
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±[0.20] / .008 THREE PLACE DECIMAL ±[0.100] / .004 DO NOT SCALE DRAWING PROPRIETARY AND CONFIDENTIAL THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF MED-ALLY, IS PROHIBITED.		TITLE: OUTER TUBING	
		SIZE B	REV 2.0
		DWG. NO. 6085	DATE 12AUG21
		SCALE: 32:1	SHEET 1 OF 1

	Drawing No:	7073	Revision:	1.0
	Part No:	7073	Created By:	G. Early
	Part Description 1:	Silicone Adhesive, MED-2000		
	Part Description 2:	NuSil MED-2000		
Med-Ally,LLC 2040 Bushy Park Road, North Bldg 6 Goose Creek, SC 29445	Supplier Part No:	MED-2000 (Self-Leveling)		
	Supplier Name:	NuSil		
	Specification Control Drawing			

Rev	ECO Number	Description	Date
1.0	22-31	Initial Release	22Nov2022

Description

- One-part, solvent-free silicone
- Cures at room temperature upon exposure to atmospheric moisture

Applications

- Well suited for use as an adhesive for bonding and sealing silicone materials
- For applications requiring the bonding of silicone to metals, urethanes and various other substrates

NuSil Technology's MED-2000 may be considered for use in human implantation for a period of greater than 29 days.



MED-2000

Silicone adhesive

DESCRIPTION

- One part, solvent-free silicone
- Cures at room temperature upon exposure to atmospheric moisture

APPLICATION

- Well suited for use as an adhesive for bonding and sealing silicone materials
- For applications requiring the bonding of silicone to metals, urethanes and various other substrates

NuSil™ MED-2000 may be considered for use in human implantation for a period of greater than 29 days.

PROPERTIES

Typical Properties	Average Result	Standard	NT-TM
Uncured:			
Appearance	Translucent	ASTM D2090	002
Extrusion Rate**	2.5 g/minute	ASTM C603	033
Tack-Free Time	12 minutes	ASTM C679	005
Cured: 72 hours minimum at ambient temperature and humidity			
Specific Gravity	1.08	ASTM D792	003
Durometer, Type A	25	ASTM D2240	006
Tensile Strength	1,375 psi (9.5 MPa)	ASTM D412	007
Elongation	800%	ASTM D412	007
Tear Strength	80 ppi (14.1 kN/m)	ASTM D624	009
Stress at 200% Strain	110 psi (0.76 MPa)	ASTM D412	007
Tissue Culture (Cytotoxicity Testing)	Pass	USP <87> ISO 10993-5	061

The above properties are tested on a lot-to-lot basis. Do not use as a basis for preparing specifications. Please [contact](#) NuSil Technology for assistance and recommendations in establishing particular specifications.

** Performed using a Semco model 250-A pneumatic gun with a 14 gauge nozzle orifice and 90 +/- 5 psi air pressure.

INSTRUCTIONS FOR USE

Apply MED-2000, supplied in cartridges, with the use of appropriate dispensing equipment. Do not store alcohol near the worksite as traces of alcohol inhibit the catalytic system of the adhesive.

Surface Preparation

Thoroughly clean surfaces being bonded or built-up with silicone adhesive using a non-oily cleaner or mild soap to remove any surface contaminants. Do not use synthetic detergents or oil-based soaps, as they may be absorbed and subsequently leach out. Rinse first with hot water, followed by a thorough rinse using distilled water. Use compatible degreasers to clean metal surfaces.

Bonding Applications

Spread a layer of silicone adhesive on one of the surfaces. Squeeze both surfaces together to bond. Apply sufficient pressure to ensure full contact without forcing the silicone adhesive from between the pieces.

Note: Some bonding applications may require the use of a primer. NuSil Technology's MED-160 is recommended. For more information on primer selection, visit www.nusil.com and review [Choosing a Silicone Primer/Adhesive System](#).

Curing Time

Curing or vulcanization time depends upon the thickness of the silicone adhesive layer, relative humidity, and accessibility of atmospheric moisture to the curing adhesive. For sections of typical thickness, a relative humidity level between 20-60% is recommended to cure the adhesive at room temperature.

Generally the adhesive forms a thick, tack-free outer skin for thick section films within a few minutes after application. The vulcanization rate slows when exposing very thin films to excessive humidity (80% relative air humidity). For films below 80 microns, the relative air humidity should be within 30% - 50%.

Because MED-2000 cures upon exposure to atmospheric moisture, keep tubes tightly closed when not in use. A plug of cured material may form in the tip of the tube. Remove or dispense the plug from the tube before using.

Non-Sterile Packaged Units

The acidic nature of MED-2000 provides a natural bactericidal effect. While containers may be relatively free of microorganisms, they can not be considered sterile unless subjected to a validated sterilization process. When the adhesive is fully cured it can withstand sterilization with ethylene oxide, dry heat, or steam autoclaving. The size and shape of fabricated articles must be considered when

Packaging

8 Gram Tube
2 Ounce Tube (59 mL)
5 Ounce Tube (148 mL)
6 Ounce Semco® Tube
12 Ounce Semco® Tube

Warranty

12 Months

establishing the conditions of sterilization. Larger quantities and larger parts may require longer periods of heating and may retain ethylene oxide longer than small parts. It is the user's responsibility to determine the out-gassing time required for a particular application if ethylene oxide sterilization methods are used.

Caution

Do not use MED-2000 in its uncured state to repair or encapsulate living tissue in the body. During curing, approximately 4-5% acetic acid (vinegar-like odor) is generated in vapor form. Avoid contact with eyes and skin, as uncured adhesive irritates. Take appropriate precautions if wearing contact lenses. In case of contact, flush eyes with water, use a dry towel to remove from skin and contact a physician. Keep out of REACH of children.

FDA MASTER FILE

A Master File for MED-2000 has been filed with the U.S. Food and Drug Administration. Customers interested in authorization to reference the Master File must [contact](#) NuSil Technology.

REACH COMPLIANCE

Please [contact](#) NuSil Technology's Regulatory Compliance department with any questions or for further assistance.

SPECIFICATIONS

Do not use the properties shown in this technical profile as a basis for preparing specifications. Please [contact](#) NuSil Technology for assistance and recommendations in establishing particular specifications.

WARRANTY INFORMATION

The warranty period provided by NuSil Technology LLC (hereinafter "NuSil Technology") is 12 months from the date of shipment when stored below 40°C in original unopened containers. Unless NuSil Technology provides a specific written warranty of fitness for a particular use, NuSil Technology's sole warranty is that the product will meet NuSil Technology's then current specification. NuSil Technology specifically disclaims all other expressed or implied warranties, including, but not limited to, warranties of merchantability and fitness for use. The exclusive remedy and NuSil Technology's sole liability for breach of warranty is limited to refund of purchase price or replacement of any product shown to be other than as warranted. NuSil Technology expressly disclaims any liability for incidental or consequential damages.

WARNINGS ABOUT PRODUCT SAFETY

NuSil Technology believes, to the best of its knowledge, that the information and data contained herein are accurate and reliable. The user is responsible to determine the material's suitability and safety of use. NuSil Technology cannot know each application's specific requirements and hereby notifies the user that it has not tested or determined this material's suitability or safety for use in any application. The user is responsible to adequately test and determine the safety and suitability for their application and NuSil Technology makes no warranty concerning fitness for any use or purpose. NuSil


Technology has completed no testing to establish safety of use in any medical application.

NuSil Technology has tested this material only to determine if the product meets the applicable specifications. (Please [contact](#) NuSil Technology for assistance and recommendations when establishing specifications.) When considering the use of NuSil Technology products in a particular application, review the latest Material Safety Data Sheet and [contact](#) NuSil Technology with any questions about product safety information.

Do not use any chemical in a food, drug, cosmetic, or medical application or process until having determined the safety and legality of the use. The user is responsible to meet the requirements of the U.S. Food and Drug Administration (FDA) and any other regulatory agencies. Before handling any other materials mentioned in the text, the user is advised to obtain available product safety information and take the necessary steps to ensure safety of use.

PATENT / INTELLECTUAL PROPERTY WARNING

NuSil Technology disclaims any expressed or implied warranty against the infringement of any domestic or international patent/intellectual property right. NuSil Technology does not warrant the use or sale of the products described herein will not infringe the claims of any domestic or international patent/intellectual property right covering the product itself, its use in combination with other products, or its use in the operation of any process.

	Drawing No:	7065	Revision:	1.0
	Part No:	7065	Created By:	J. Getsinger
	Part Description 1:	Loctite M-11FL		
	Part Description 2:	Urethane Adhesive		
Med-Ally,LLC 2040 Bushy Park Road, North Bldg 6 Goose Creek, SC 29445	Supplier Part No:	235029		
	Supplier Name:	R.S. Hughes/Henkel		
	Specification Control Drawing			

Rev	ECO Number	Description	Date
1.0	ECO 22-28	Initial Release	4Nov22



Technical Information

Agency Approvals / Certificates / Specifications	ISO 10993
Cure Type	Room Temperature (Ambient) Cure
Key Characteristics	Flexible: Highly Flexible, Peel Strength: High, Peel Strength: Viscosity: Low Viscosity
Number of Components	2 Part
Physical Form	Liquid
Shear Strength, Aluminum (etched)	1850.0 psi
Shear Strength, Steel (grit blasted)	160.0 psi
Substrates	Glass, Metal, Plastic
Mixed	
Color, Mixed	Clear; Ultra Clear
Resin	
Color, Resin	Clear
Hardener	
Color, Hardener	Clear