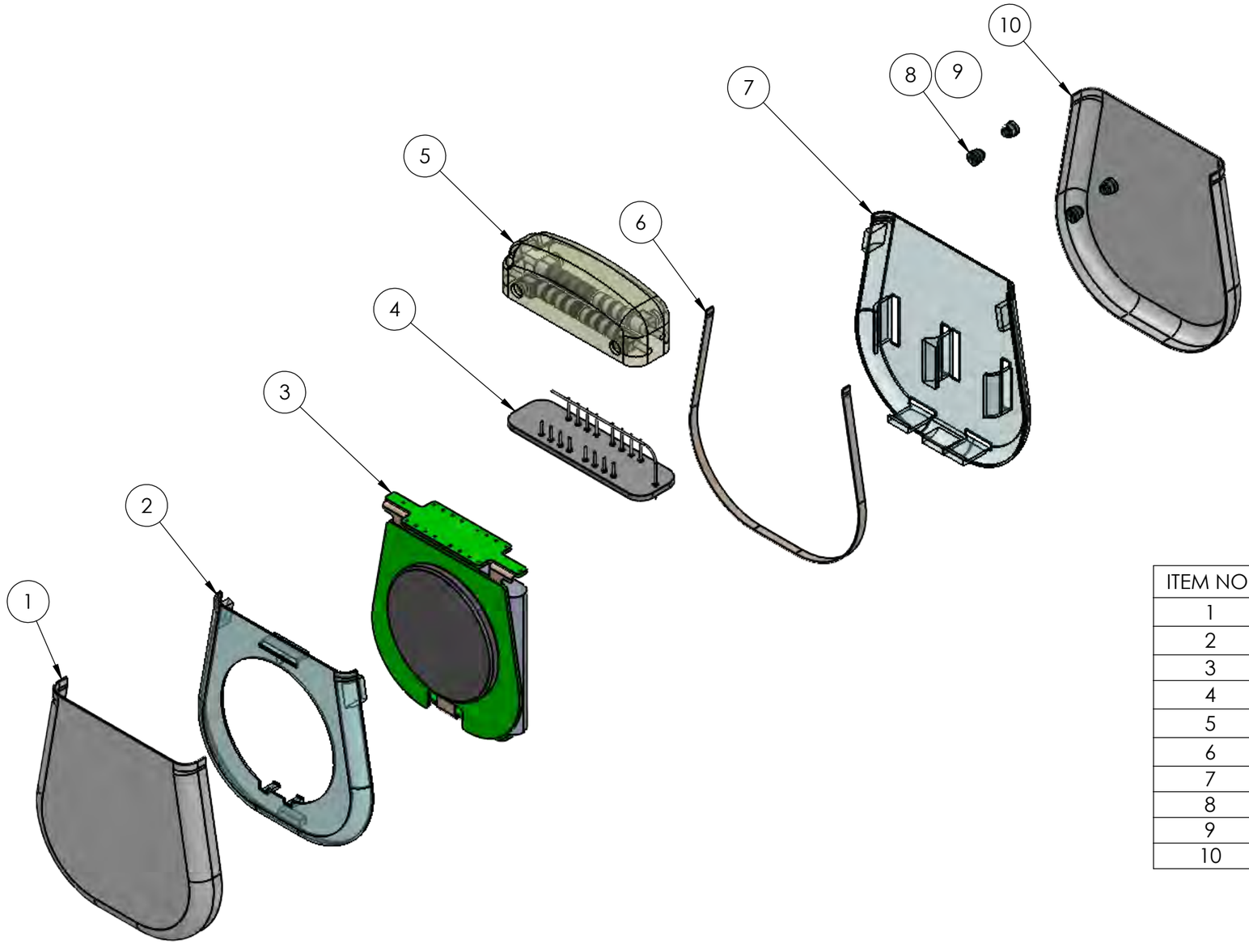
REVISIONS				
REV.	ECO	DESCRIPTION	DRAWN BY	DATE



ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	XXXXX	TOP ENCLOSURE	1
2	XXXXX	TOP NEST	1
3	XXXXX	PWB ASSEMBLY	1
4	XXXXX	LIDTHROUGH ASSEMBLY	1
5	XXXXX	MOLDED HEADER ASSEMBLY	1
6	XXXXX	WELD BAND	1
7	XXXXX	BOTTOM NEST	1
8	XXXXX	SEAL PLUG	4
9	XXXXX	#2-56 X .08 SETSCREW	4
10	XXXXX	BOTTOM ENCLOSURE	1

NEXT ASSEMBLY

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN [MM] / INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ±0.5 DEG BEND ±
TWO PLACE DECIMAL ±[0.2] / .008
THREE PLACE DECIMAL ±[0.1] / .004

DO NOT SCALE DRAWING

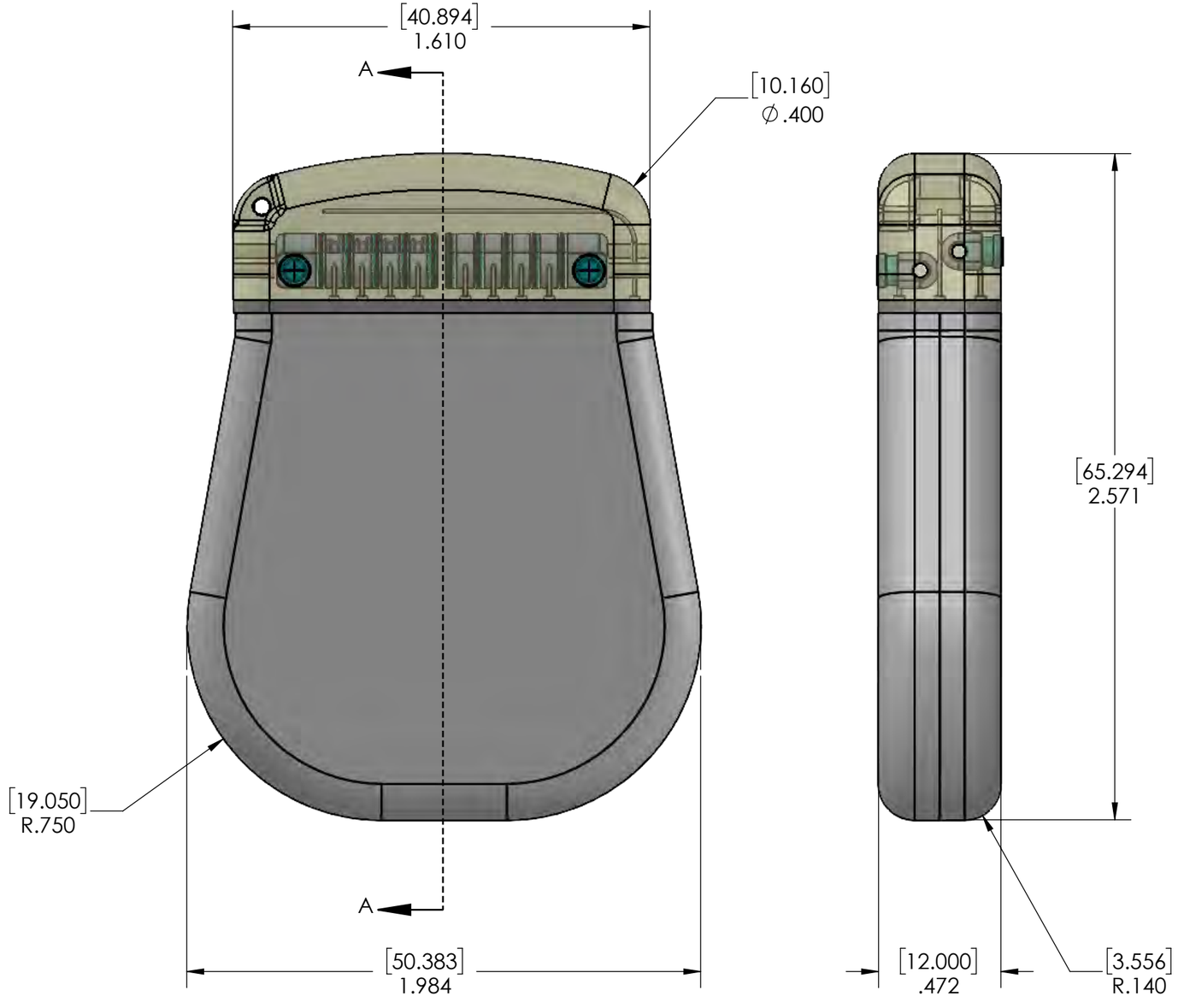
MED-ALLY LLC

TITLE:

12 MM HORNET TOP ASSEMBLY

SIZE	DWG. NO.	REV
B	XXXXX	0.4

SCALE: 1:5 SHEET 1 OF 2

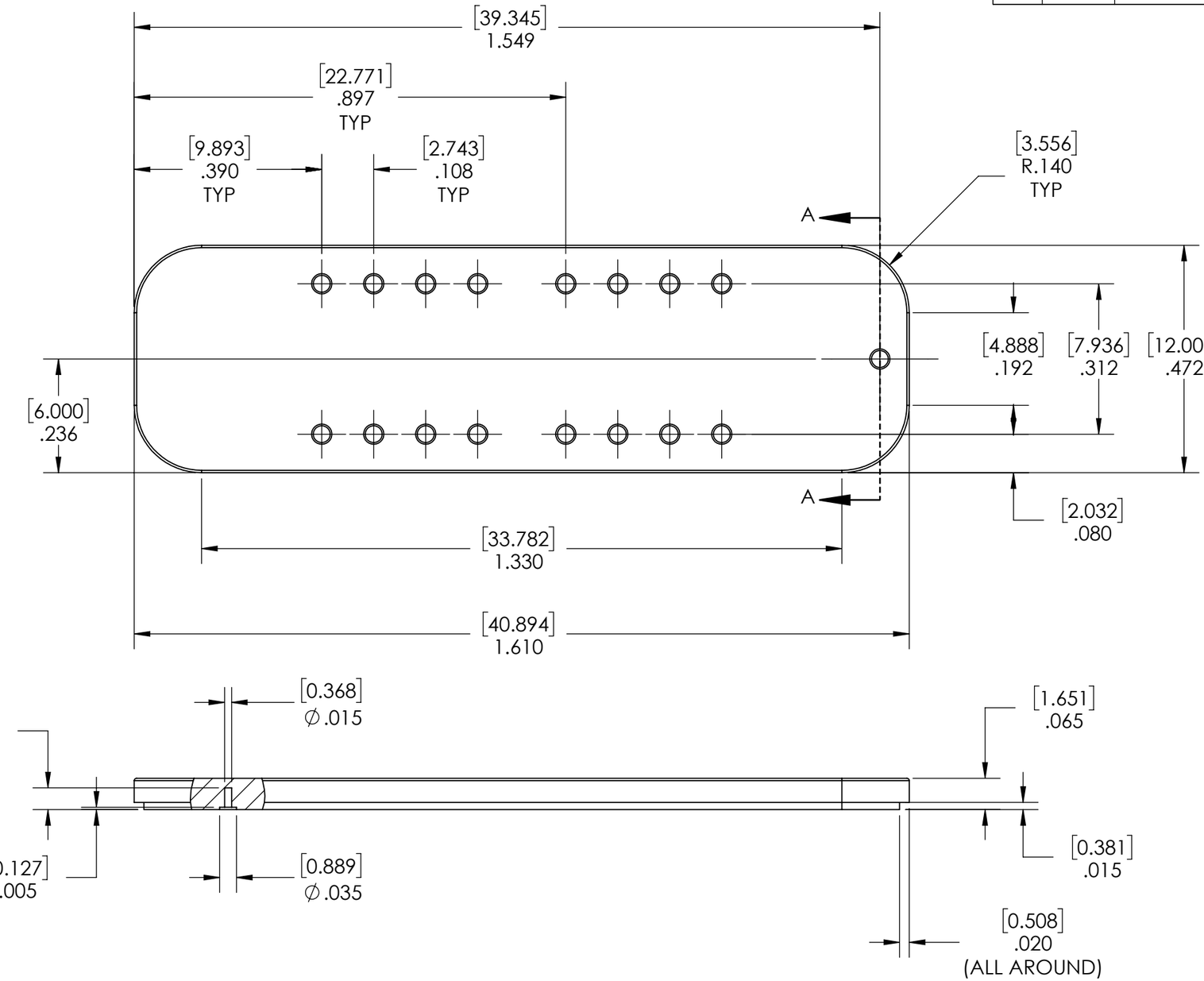


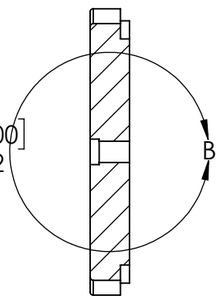
SECTION A-A
SCALE 2 : 1

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±0.5 DEG BEND ± TWO PLACE DECIMAL ±[0.2] / .008 THREE PLACE DECIMAL ±[0.1] / .004 DO NOT SCALE DRAWING	MED-ALLY LLC TITLE: 12 MM HORNET TOP ASSEMBLY
PROPRIETARY AND CONFIDENTIAL THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY LLC. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF, MED-ALLY LLC, IS PROHIBITED.	SIZE B | DWG. NO. XXXXX | REV 0.4 SCALE: 1:1 | SHEET 2 OF 2

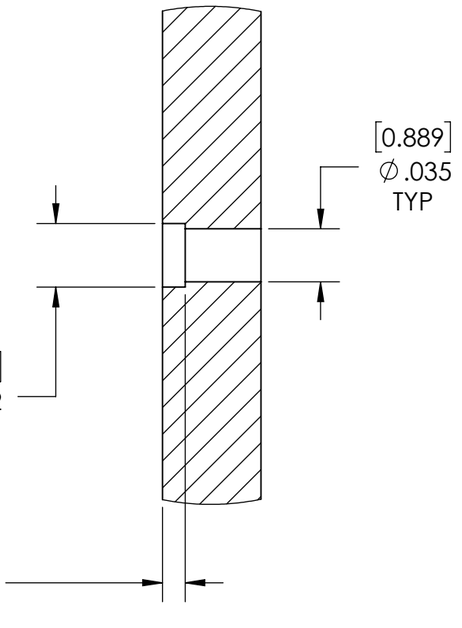
NEXT ASSEMBLY

REVISIONS				
REV.	ECO	DESCRIPTION	DRAWN BY	DATE





SECTION A-A
SCALE 4 : 1



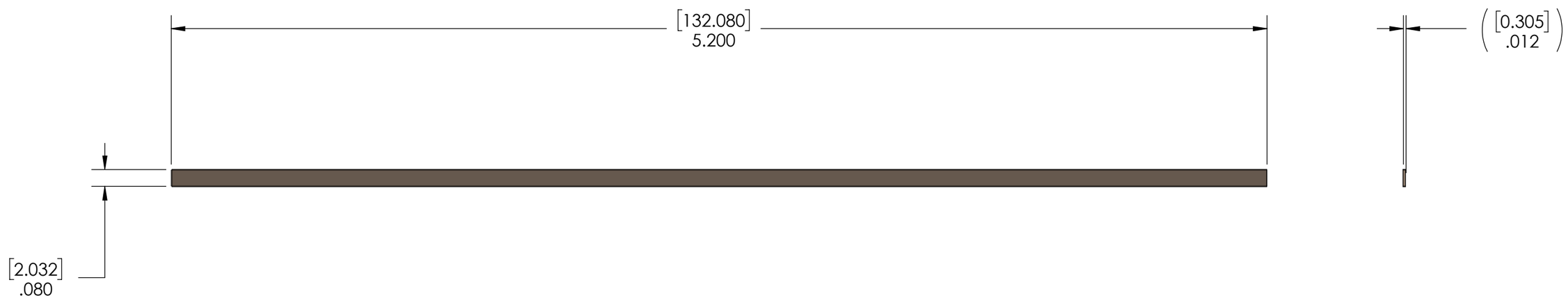
DETAIL B
SCALE 10 : 1

NOTES:
UNLESS OTHERWISE SPECIFIED:

1. MATERIAL: TITANIUM, GRADE 23, PER ASTM-FI36.
2. TOLERANCES ON ALL DIMENSIONS TO BE +/-.003 FOR PLATE.

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±0.5 DEG BEND ± TWO PLACE DECIMAL ±[0.2] / .008 THREE PLACE DECIMAL ±[0.1] / .004 DO NOT SCALE DRAWING	MED-ALLY LLC TITLE: 12 MM LIDTHROUGH PLATE
PROPRIETARY AND CONFIDENTIAL THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY LLC. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF, MED-ALLY LLC, IS PROHIBITED.	SIZE B · DWG. NO. 6164 · REV 0.4 SCALE: 2:1 · SHEET 1 OF 1
NEXT ASSEMBLY	

REVISIONS				
REV.	ECO	DESCRIPTION	DRAWN BY	DATE



NOTES:
UNLESS OTHERWISE SPECIFIED:

1. MATERIAL: .010 - .012 THICK GRADE 2 TITANIUM PER ASTM B265.
2. DIMENSIONAL VERIFICATION METHOD TO BE DETERMINED BETWEEN MED-ALLY AND SUPPLIER.
3. PARTS ARE TO BE CLEAN AND FREE OF DIRT, GREASE AND OTHER PROCESS CONTAMINATES.
4. VENDOR SHALL SUPPLY MATERIAL CERTIFICATIONS WITH MATERIAL LOT NUMBERS USED IN FABRICATION OF PARTS.

NEXT ASSEMBLY

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN [MM] / INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ±0.5 DEG BEND ±
TWO PLACE DECIMAL ±[0.2] / .008
THREE PLACE DECIMAL ±[0.1] / .004

DO NOT SCALE DRAWING

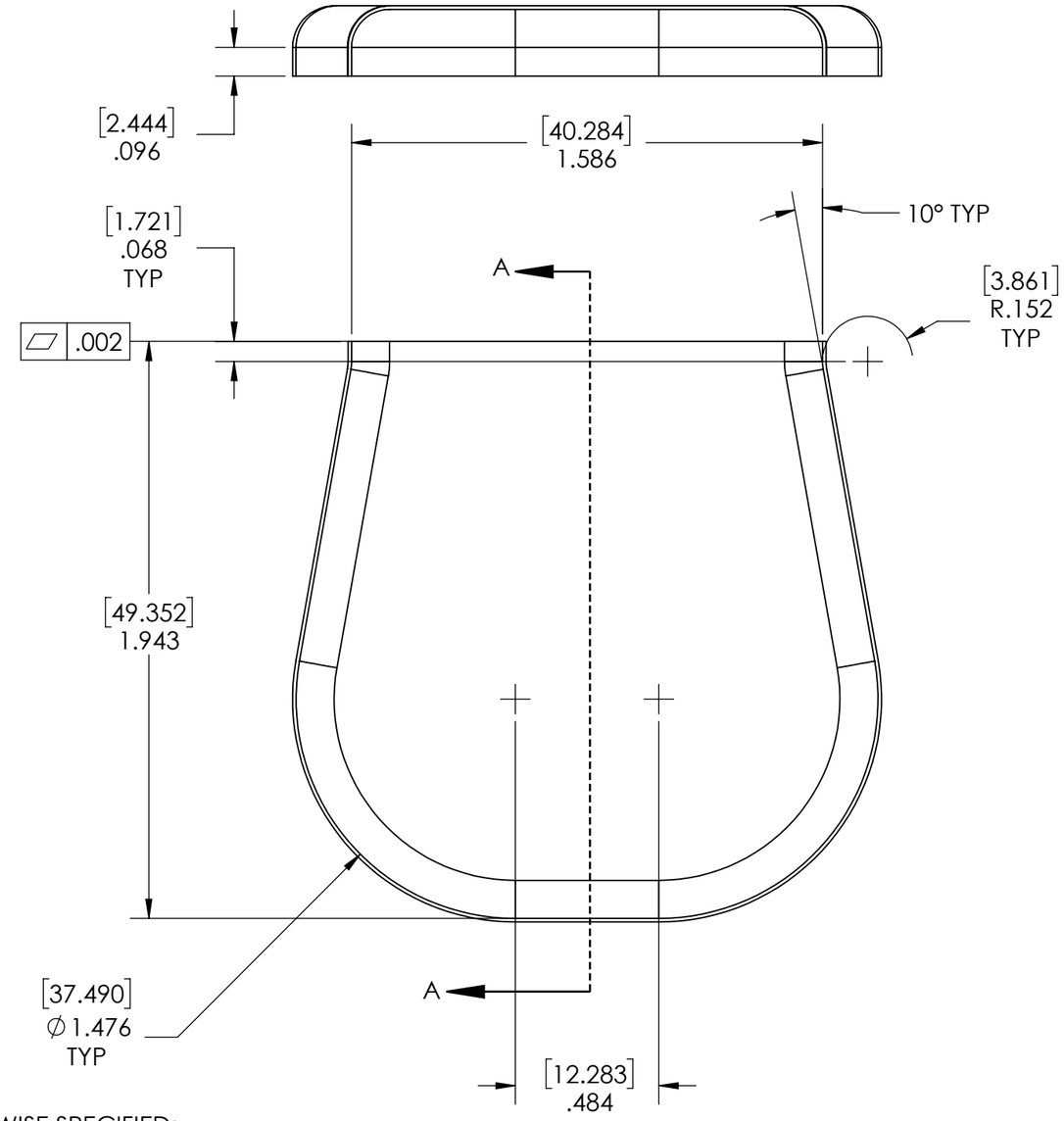
MED-ALLY LLC

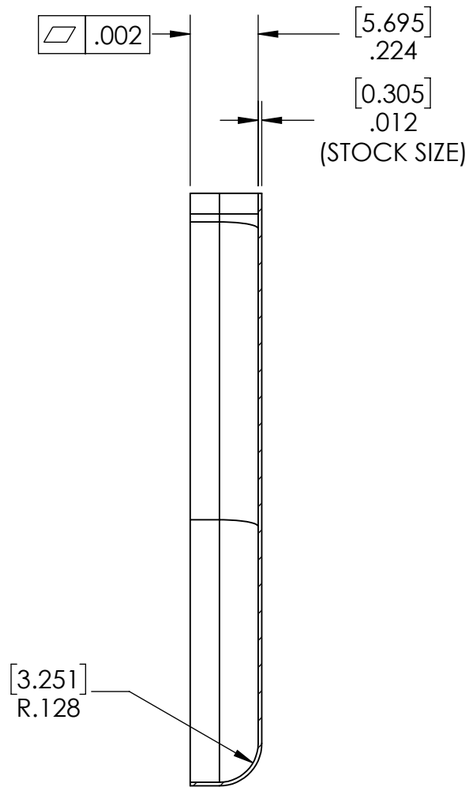
TITLE:

WELD BAND

SIZE	DWG. NO.	REV
B	6165	0.3
SCALE: 2:1		SHEET 1 OF 1

REVISIONS				
REV.	ECO	DESCRIPTION	DRAWN BY	DATE





SECTION A-A

NOTES:
UNLESS OTHERWISE SPECIFIED:

1. MATERIAL: GRADE 23 TITANIUM PER ASTM B265.
2. ALL DIMENSIONS ARE TO INSIDE SURFACES.
3. A LEAD IN ANGLE FROM 0.5 TO 1.5 DEGREES IS ACCEPTABLE.
4. VERIFICATION METHODS TO BE DETERMINED BETWEEN CUSTOMER AND SUPPLIER.
5. PARTS ARE TO BE CLEAN AND FREE OF DIRT, GREASE AND OTHER PROCESS CONTAMINATES.
6. VENDOR SHALL SUPPLY MATERIAL CERTIFICATIONS WITH MATERIAL LOT NUMBERS USED IN FABRICATION OF PARTS.
7. DIMENSIONAL INSPECTION PERFORMED USING 4.4 LB [2.0 KG] WEIGHT APPLIED.

NEXT ASSEMBLY

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN [MM] / INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ±0.5 DEG BEND ±
TWO PLACE DECIMAL ±[0.2] / .008
THREE PLACE DECIMAL ±[0.1] / .004

DO NOT SCALE DRAWING

MED-ALLY LLC

TITLE:

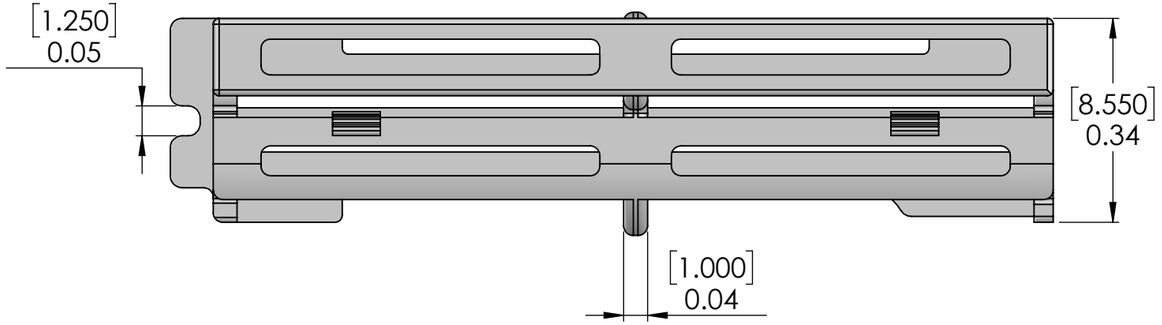
12.00 MM ENCLOSURE
(TOP AND BOTTOM)

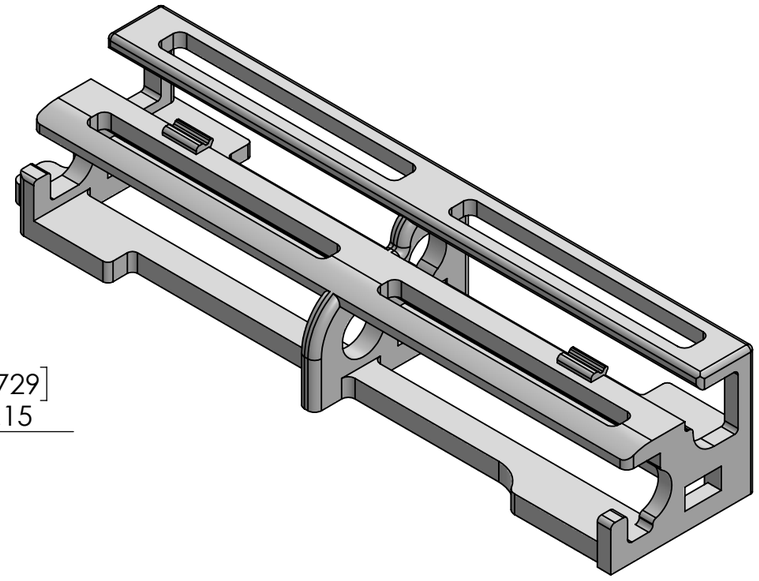
SIZE	DWG. NO.	REV
B	6163	0.2

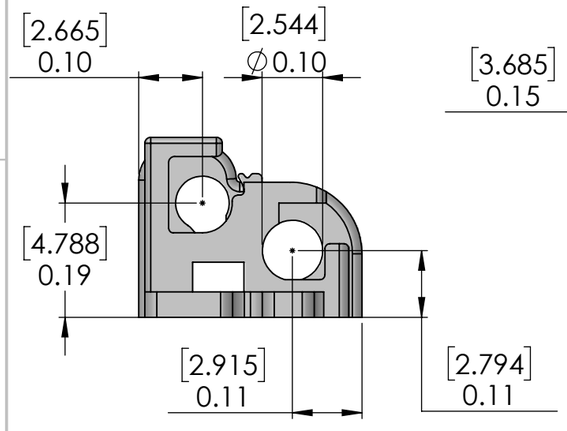
SCALE: 2:1 SHEET 1 OF 1

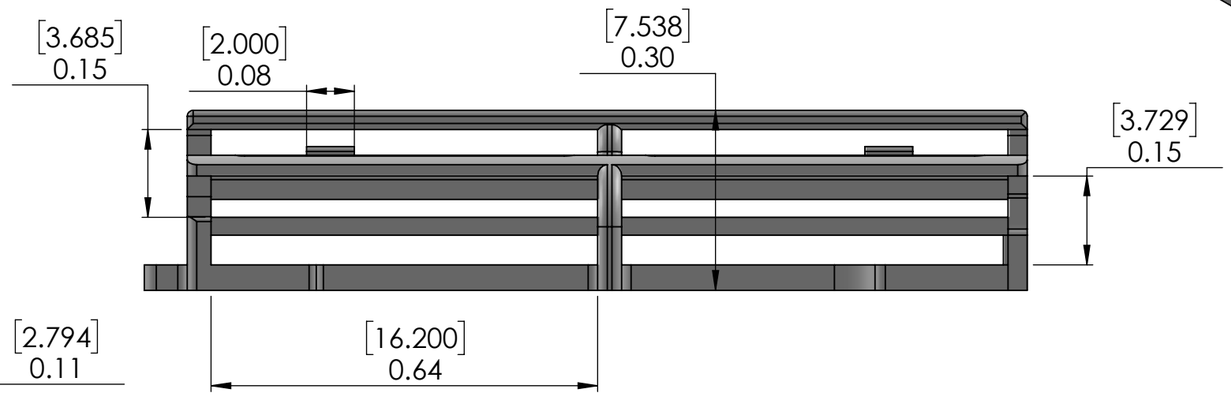
DRAFT

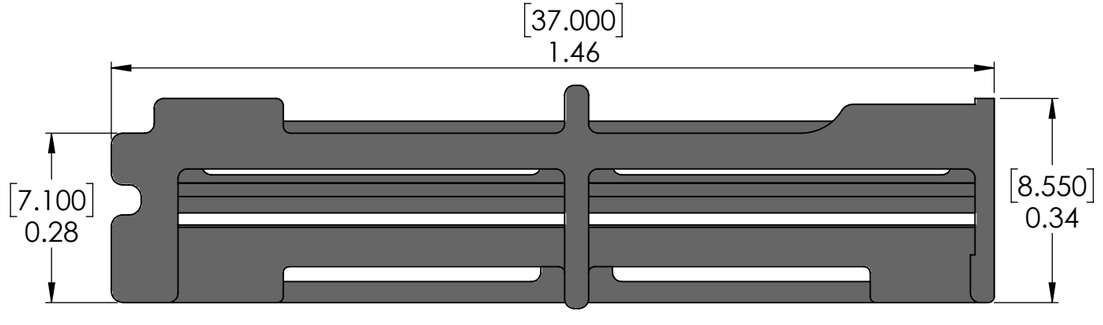
REVISIONS				
REV.	ECO	DESCRIPTION	DRAWN BY	DATE
0.1		INITIAL RELEASE	F. ROBERTS	16 MAR 2023











Notes:

1. Material: Biomed Amber
2. Reference Model: 8XXX, Dropdown Scaffold, Rev 1.0

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

MED-ALLY

TITLE:

Dropdown Scaffold

SIZE	DWG. NO.	REV
B	6174	0.1
SCALE: 5:1		SHEET 1 OF 1

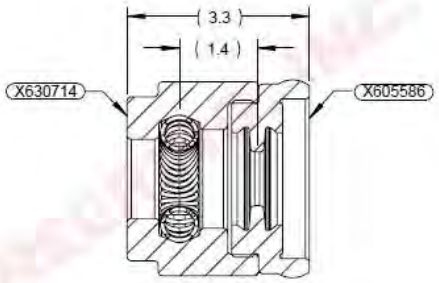
MED - ALLY	**Drawing No:**	7001	**Revision:**	2.0
	Part No:	7001	**Created By:**	C. Mannarino
	Part Description 1:	BalSeal 2.8mm pitch contact		
	Part Description 2:	Balseal Sygnus Neuro 2.8mm Pitch Contact		
Med-Ally,LLC 2040 Bushy Park Road, North Bldg 6 Goose Creek, SC 29445	**Supplier Part No:**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

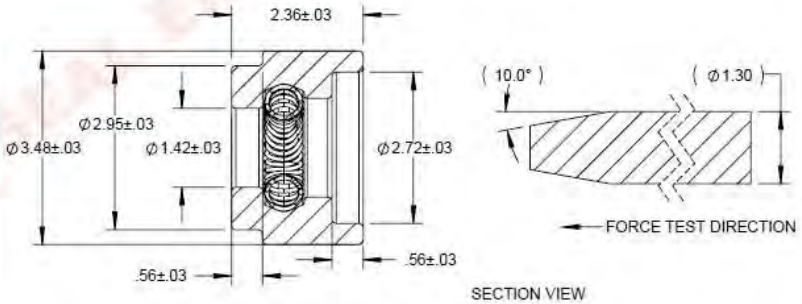
NOTES UNLESS OTHERWIES SPECIFIED

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

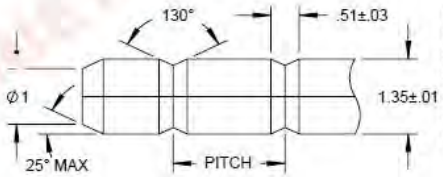
1. PROJECT INFORMATION
   ENGINEERING REQUEST: 40958
   OPPORTUNITY: 34517
   OPPORTUNITY DESCRIPTION: MED-ALLAY - UPDATED HOUSING DRAWINGS
2. CUSTOMER SUPPLIED APPLICATION DATA
   EQUIPMENT TYPE: MEDICAL ELECTRONICS
3. THE CUSTOMER IS URGED TO READ RELEVANT BAL SEAL DOCUMENTS LOCATED AT WWW.BALSEAL.COM/TECHNICAL-LIBRARY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



SECTION MATE REFERENCE



SECTION VIEW



PITCH ALIGNMENT CORE PIN

PART DESCRIPTION	MATERIAL
101 DESIGN SPRING	PLATINUM IRIDIUM 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. TOLERANCES: DECIMALS: X. = ±.5, X.X = ±.3, X.XX = ±.05; ANGULAR: X° = ±2°. THIRD ANGLE PROJECTION

DRAWN	J.KOMPA	2020-03-10
PROPOSED	J.KOMPA	2020-03-10
ENG	E.FORT	2020-03-10
CHECK	M.BALTA	2020-03-10
SALES	O.PASCARELLI	2020-03-10

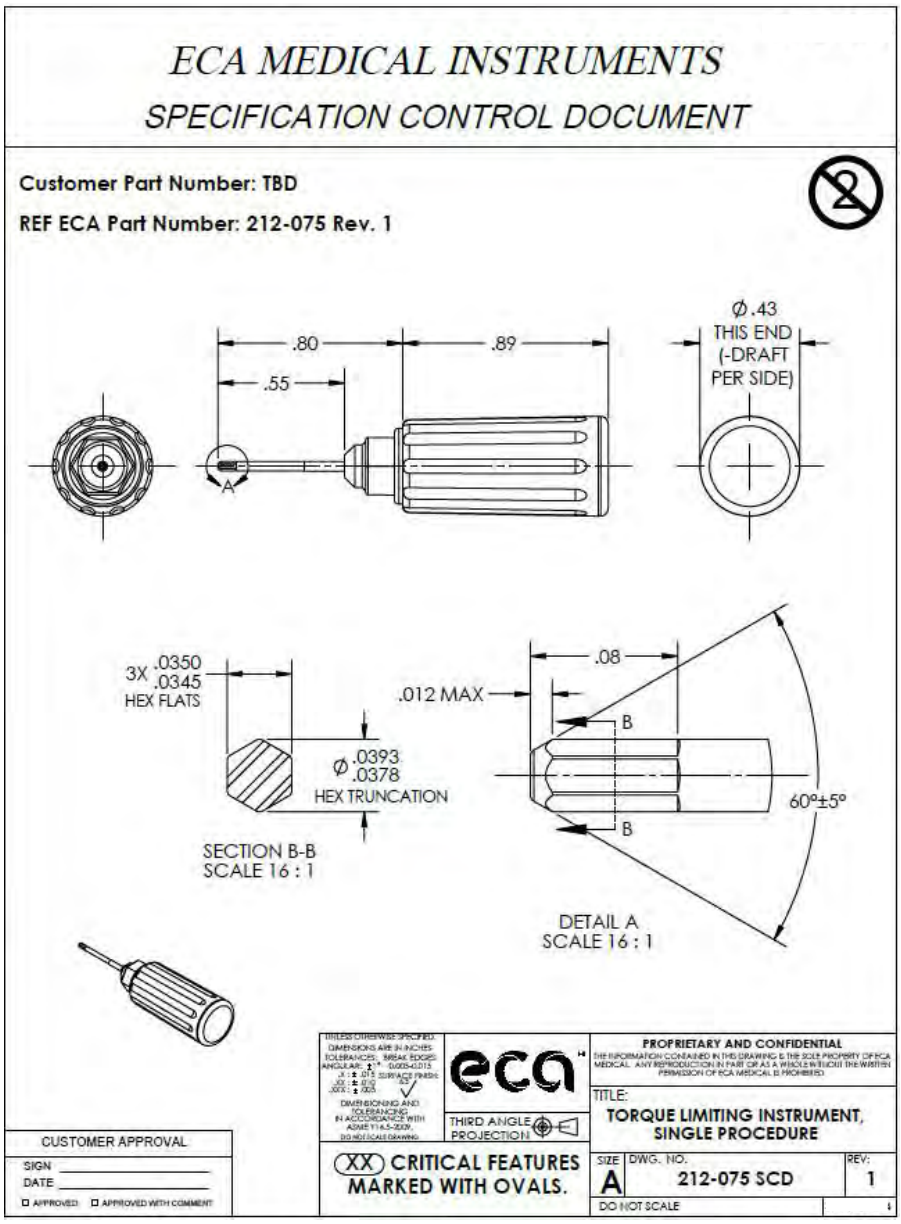
CUSTOMER NAME: MED-ALLY
DRAWING NAME: INTERFACE CONTROL DRAWING
SCALE: NONE
SIZE: A
PAGE No.: 1 of 2
CAGE CODE: 09055
DRAWING No.: X630714
PROJ REPORT No.: -
REV.: A

BAL SEAL ENGINEERING INC
Bal Seal Engineering, Inc.
19650 Pauling
Foothill Ranch, CA 92610
Tel: (949)460-2100
Fax: (949)460-2300
Web: www.balseal.com

O-1596-ICDA REV A

MED - ALLY	**Drawing No:**	7006	**Revision:**	2.0
	Part No:	7006	**Created By:**	C. Mannarino
	Part Description 1:	Torque Driver 5 in-oz Hex		
	Part Description 2:	Model 212-075 Torque Screwdriver		
Med-Ally,LLC 2040 Bushy Park Road, North Bldg 6 Goose Creek, SC 29445	**Supplier Part No:**	212-075, Rev 1.0		
	Supplier Name:	ECA Medical		
	Specification Control Drawing			

Rev	ECO Number	Description	Date
2.0	20-25	Change torque value from 12 in-oz to 5 in-oz	18May20



MED - ALLY	**Drawing No:**	7006	**Revision:**	2.0
	Part No:	7006	**Created By:**	C. Mannarino
	Part Description 1:	Torque Driver 5 in-oz Hex		
	Specification Control Drawing			

ECA MEDICAL INSTRUMENTS

SPECIFICATION CONTROL DOCUMENT

1. INTENDED USE: TO TIGHTEN SCREW(S) OF NEUROSTIMULATOR DEVICE DURING SURGICAL PROCEDURE.

2. TORQUE SPECIFICATION:
   UNI-DIRECTIONAL:
   5.0 +/- 0.5 OZ-IN IN THE CLOCKWISE DIRECTION
   POSITIVE IN THE COUNTERCLOCKWISE DIRECTION

3. APPEARANCE:
   EXTERIOR SURFACES ARE SMOOTH AND FREE OF OBVIOUS SCRATCHES, SINK MARKS, CRACKS, FLASH, AND SPLAY PER EMS-0001.

4. CAP:
   INSTALLED CAP HAS NO LOGO.

5. MATERIALS:
   NOSE AND HANDLE: ULTEM HU1100-8H9D402, COLOR: WHITE
   SHAFT: CUSTOM 455 STAINLESS STEEL PER ASTM ASM 5617, TURNED FINISH, H-900 CONDITION, PASSIVATED PER AMS 2700
   INTERNAL METAL COMPONENTS: 302 STAINESS STEEL PER ASTM A313, AND 17-7 PH STAINLESS STEEL PER AMS 5529

6. STERILIZATION:
   DEVICE IS PROVIDED NON-STERILE.

7. SHELF LIFE:
   TWO (2) YEAR(s) IN A TEMPERATURE CONTROLLED ENVIRONMENT (FROM THE DATE OF MANUFACTURE)

8. SERVICE LIFE:
   THIS DEVICE IS SINGLE USE, AND IS NOT INTENDED TO BE REPROCESSED (CLEANED, DISINFECTED/STERILIZED) AND/OR USED ON ANOTHER PATIENT.

9. DEVICE FEEDBACK:
   TEN (10) AUDIBLE INDICATIONS AT TORQUE LIMIT, PER ONE (1) FULL ROTATION.

10. PACKAGING:
    PACKAGED WITHIN SEE-THRU VACUUM-FORMED CONTAINER HOLDING SIXTY (60) INSTRUMENTS. AN IDENTIFICATION LABEL IS PLACED ON EACH CONTAINER WITH THE FOLLOWING INFORMATION, AT A MINIMUM: CUSTOMER OR ECA PART NUMBER, CUSTOMER ORDER NUMBER, AND MANUFACTURING LOT NUMBER.

11. CHEMICAL RESIDUES / BIOCOMPATIBILITY:
    THIS DEVICE HAS BEEN CLEANED TO REMOVE PROCESSING CHEMISTRIES AND GROSS SIZED PARTICLES; HOWEVER, IT IS RECOMMENDED THAT FURTHER BIOCOMPATIBILITY EVALUATION OF THIS DEVICE IN ACCORDANCE TO THE LATEST ISSUE OF ISO 10993-1 BIOLOGICAL EVALUATION OF MEDICAL DEVICES - PART 1: EVALUATION AND TESTING WITHIN A RISK MANAGEMENT PROCESS, CONTACT DURATION 'A' LIMITED (≤24H), SURFACE DEVICE, INTACT SKIN AND MUCOSAL MEMBRANE ONLY BE COMPLETED.

UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN INCHES
TOLERANCES: BREAK EDGES
ANGULAR: ± 1° 0.005-0.015
.X: ± .015 SURFACE FINISH
.XX: ± .010 63
.XXX: ± .005
DIMENSIONING AND TOLERANCING IN ACCORDANCE WITH ASME Y14.5-2009
DO NOT SCALE DRAWING

eca™

THIRD ANGLE PROJECTION

PROPRIETARY AND CONFIDENTIAL
THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF ECA MEDICAL. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF ECA MEDICAL IS PROHIBITED.

TITLE:
TORQUE LIMITING INSTRUMENT, SINGLE PROCEDURE

(XX) CRITICAL FEATURES MARKED WITH OVALS.

SIZE	DWG. NO.	REV:
A	212-075 SCD	1

DO NOT SCALE

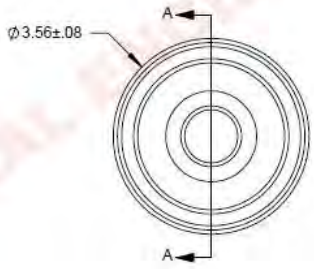
MED - ALLY	**Drawing No:**	7002	**Revision:**	2.0
	Part No:	7002	**Created By:**	C. Mannarino
	Part Description 1:	BalSeal Seal		
	Part Description 2:	BalSeal Sygnus Neuro Seal		
Med-Ally,LLC 2040 Bushy Park Road, North Bldg 6 Goose Creek, SC 29445	**Supplier Part No:**	X605586 Rev B		
	Supplier Name: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

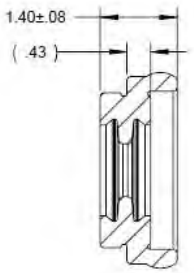
Rev	ECO Number	Description	Date
1.0	19-52	Initial release	12 Nov 19
2.0	19-14	Replace Newronika ICD with Med-Ally ICD.	23Mar2020

NOTES UNLESS OTHERWIES SPECIFIED

ECO#	DATE	APPROVED
61463	2019-03-18	J.KOMPA

1. PROJECT INFORMATION
   ENGINEERING REQUEST: 22119
   OPPORTUNITY: 21711
   OPPORTUNITY DESCRIPTION: SYGNUS STANDARD NEUR
2. CUSTOMER SUPPLIED APPLICATION DATA
   EQUIPMENT TYPE: MEDICAL ELECTRONICS
3. THE CUSTOMER IS URGED TO READ RELEVANT BAL SEAL DOCUMENTS LOCATED AT WWW.BALSEAL.COM/TECHNICAL-LIBRARY
4. UNCONTROLLED IF PRINTED. PLEASE CONTACT BAL SEAL ENGINEERING TO CONFIRM REVISION LEVEL.
5. CERTIFICATE OF COMPLIANCE REQUIRED.





SECTION A-A

PART DESCRIPTION	MATERIAL
MEDICAL SEAL	IMPLANTABLE SILCONE RUBBER MED-4850

UNLESS OTHERWISE SPECIFIED DIMENSIONS ARE IN MILLIMETERS
TOLERANCES: DECIMALS: X. = ±.5, X.X = ±.3, X.XX = ±.05; ANGULAR: X° = ±2°
THIRD ANGLE PROJECTION

DRAWN	J.KOMPA	2014-01-14
PROPOSED	J.KOMPA	2014-01-14
ENG	D.FOON	2014-01-14
CHECK	F.DILMAGHANIAN	2014-01-14
SALES	M.RUSSELL	2014-01-14

CUSTOMER NAME: MED-ALLY
SCALE: NONE
DRAWING NAME: INTERFACE CONTROL DRAWING
SIZE: A
PAGE No.: 1 of 2
CAGE CODE: 09055
DRAWING No.: X605586
PROJ REPORT No.: -
REV.: B

BAL SEAL ENGINEERING INC.
Bal Seal Engineering, Inc.
19650 Pauling
Foothill Ranch, CA 92610
Tel: (949)460-2100
Fax: (949)460-2300
Web: www.balseal.com

O-1596-ICDA REV A

MED - ALLY	**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

EPOXY TECHNOLOGY

EPO-TEK® 301

Technical Data Sheet
For Reference Only
Spectrally Transparent Epoxy

Date:	September 2017		**Recommended Cure: 65°C / 2 Hours**
Rev:	X		
No. of Components:	Two		Minimum Alternative Cure(s):
Mix Ratio by Weight:	20 : 5		*May not achieve performance properties listed below*
Specific Gravity:	Part A: 1.15	Part B: 0.87	65°C / 1 Hour
Pot Life:	1-2 Hours		23°C / 24 Hours
Shelf Life- Bulk:	One year at room temperature		

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	

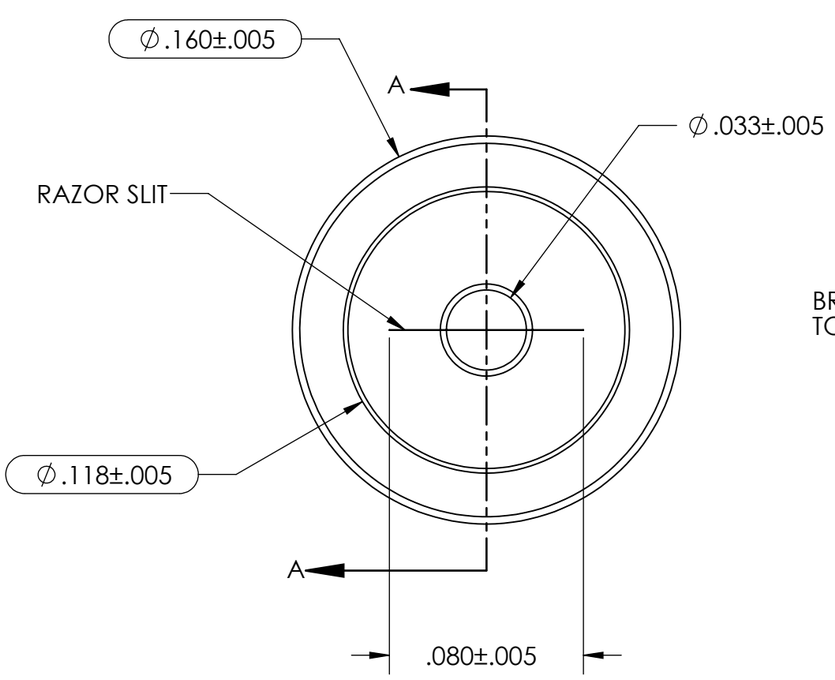
OPTICAL PROPERTIES @ 23°C:		
Spectral Transmission:	≥ 99% @ 382-980	nm
	≥ 97% @ 980-1,640	nm
	≥ 95% @ 1,640-2,040	nm
Refractive Index:	1.519 @ 589	nm

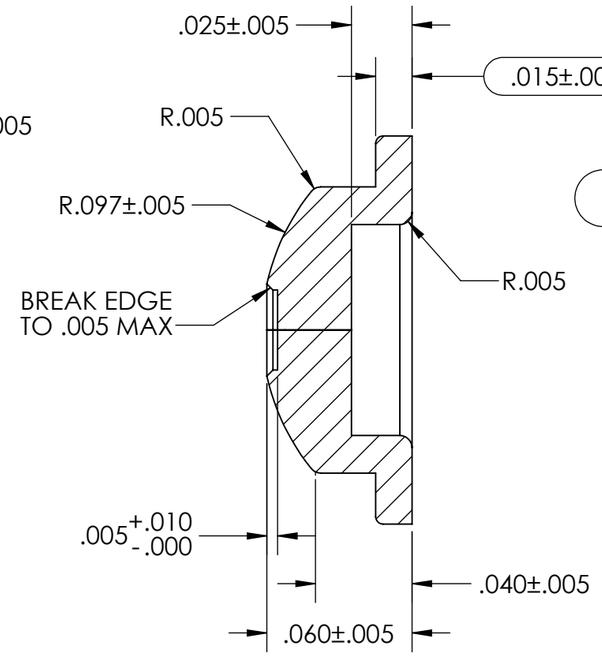
Epoxies and Adhesives for Demanding Applications™

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.

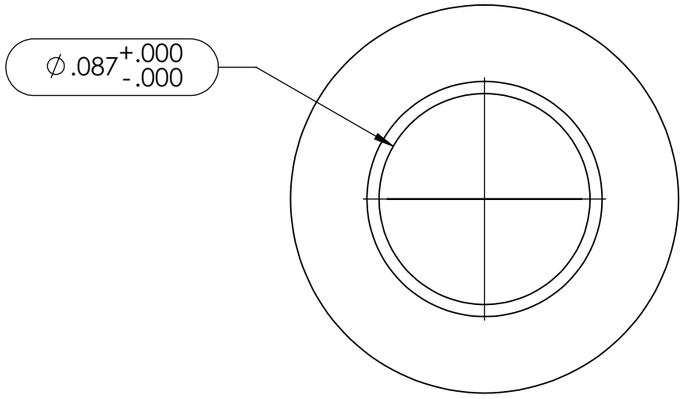
EPOXY TECHNOLOGY, INC.
14 FORTUNE DRIVE, BILLERICA, MA 01821 (978) 667-3805, FAX (978) 663-9782
www.epotek.com

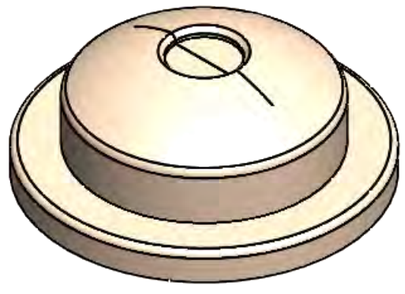
REVISIONS				
REV.	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	20-11	INITIAL RELEASE	S. BEHAN	2/21/20
4.0	20-65	DELETED NOTES 5 AND 6, NO REVISIONS 2 OR 3	S. BEHAN	12/17/20





SECTION A-A
SCALE 16 : 1



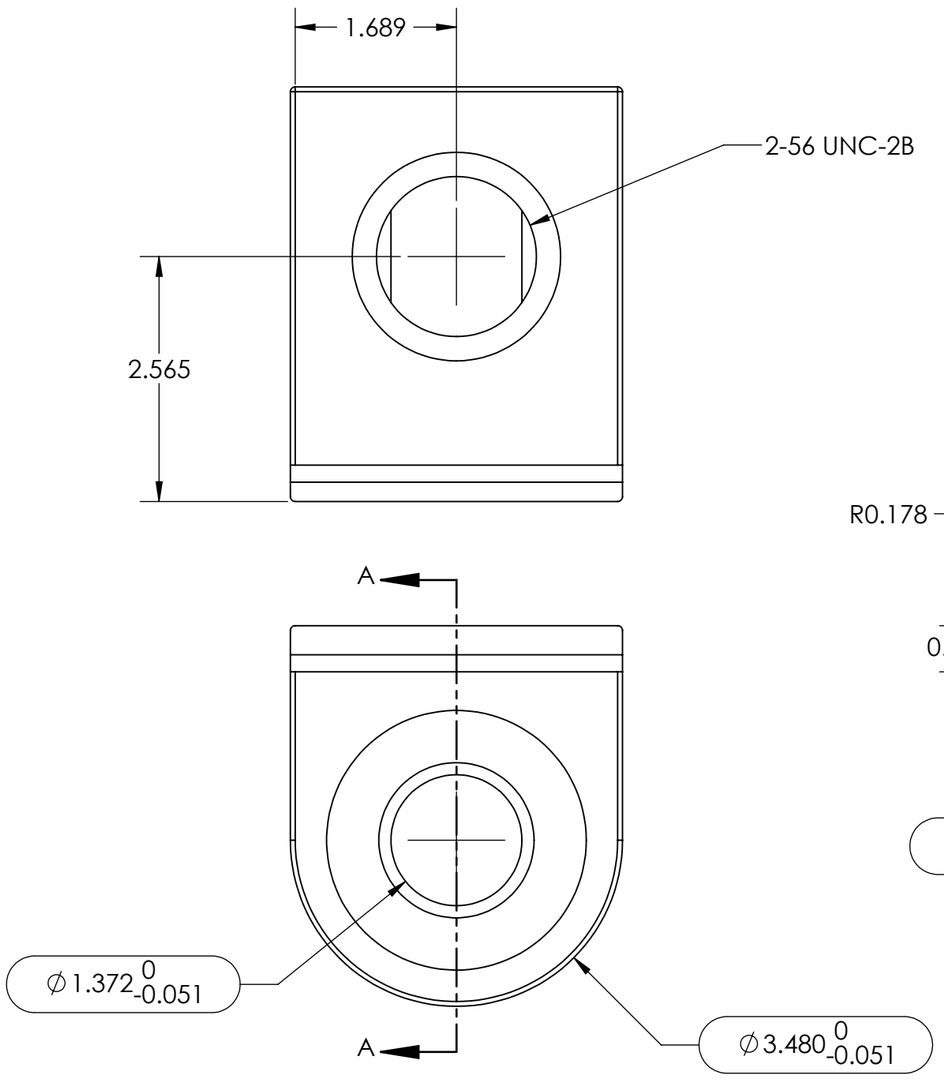


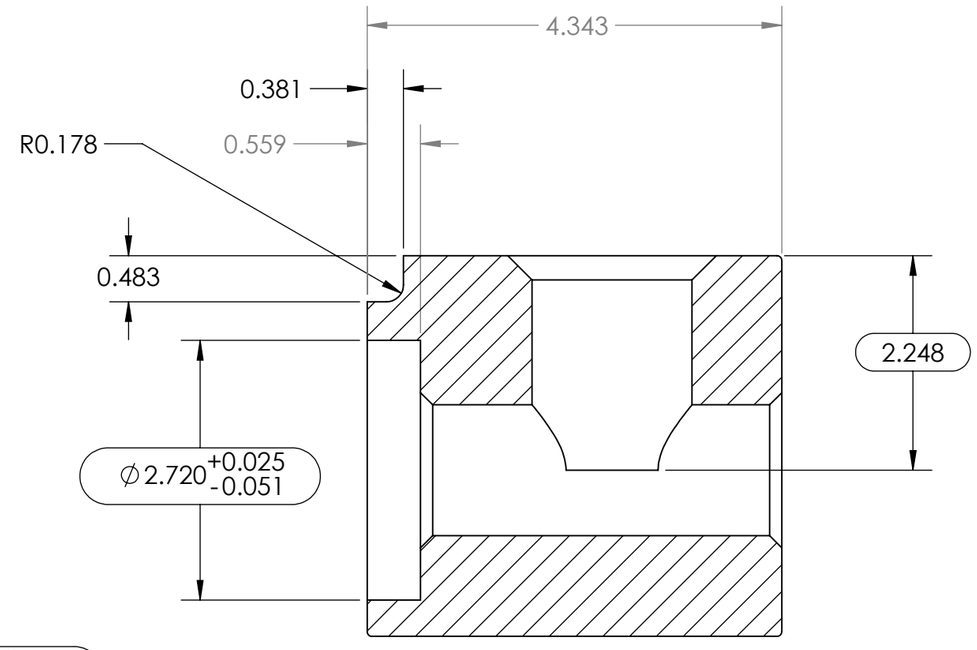
NOTES:
UNLESS OTHERWISE SPECIFIED:

1. MATERIAL: NUSIL, MED-4840.
2. TYPICAL DRAFT ANGLE FROM THE PARTING LINE, OR POINT OF DIMENSION SHOWN, SHALL NOT EXCEED .50 DEGREES.
3. PARTS ARE TO BE CLEAN AND FREE OF DIRT, GREASE AND OTHER PROCESS CONTAMINATES.
4. CRITICAL DIMENSIONS ON DRAWINGS ARE ENCLOSED IN OVALS.
5. MATERIAL CERTIFICATION, SOURCE, AND LOT NUMBER USED TO MANUFACTURE THESE PARTS SHALL BE RECORDED BY SUPPLIER.
6. PRODUCTION RUNS INSPECTED TO ANSI/ASQ Z1.4 (2013) GENERAL INSPECTION LEVEL I WITH AN AQL OF 2.5.
7. SHIPPED PRODUCT SHALL BE PACKAGED TO PREVENT DAMAGE TO PARTS, AND LABELED WITH MED-ALLY PART NUMBER, NAME, AND SUPPLIERS WORK ORDER NUMBER(s) OR PRODUCTION LOT NUMBER(s), AND CONTAIN A CERTIFICATE OF CONFORMANCE.
8. THE CERTIFICATE OF CONFORMANCE SHALL STATE THAT SHIPPED PRODUCTS MEET ALL CRITERIA ON MED-ALLY DRAWING,AND INSPECTION AND MATERIAL RECORDS ARE KEPT BY SUPPLIER FOR AT LEAST 10 YEARS. DATA MUST BE MADE AVAILABLE TO MED-ALLY IF REQUESTED.

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	MED-ALLY TITLE: SEAL PLUG
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. 6018 | REV 4.0 SCALE: 24:1 | SHEET 1 OF 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:

DIMENSIONS ARE IN MM
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ±.5 BEND ±
TWO PLACE DECIMAL ±0.200
THREE PLACE DECIMAL ±0.100

DO NOT SCALE DRAWING

MED-ALLY

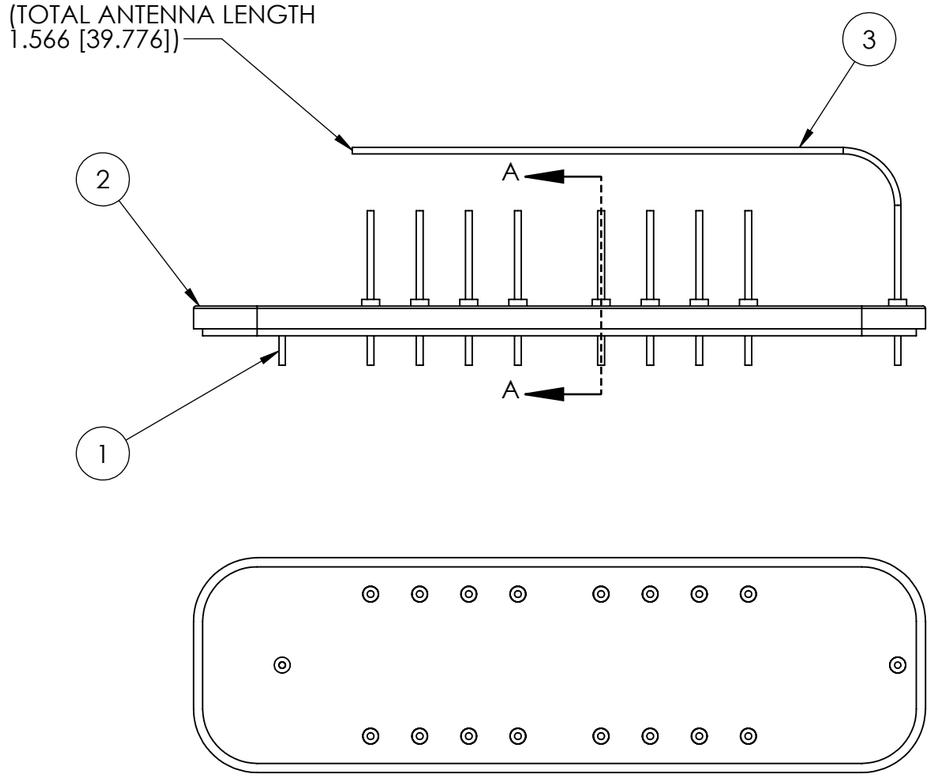
TITLE:

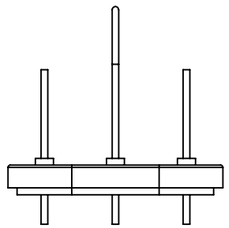
CONNECTOR BLOCK

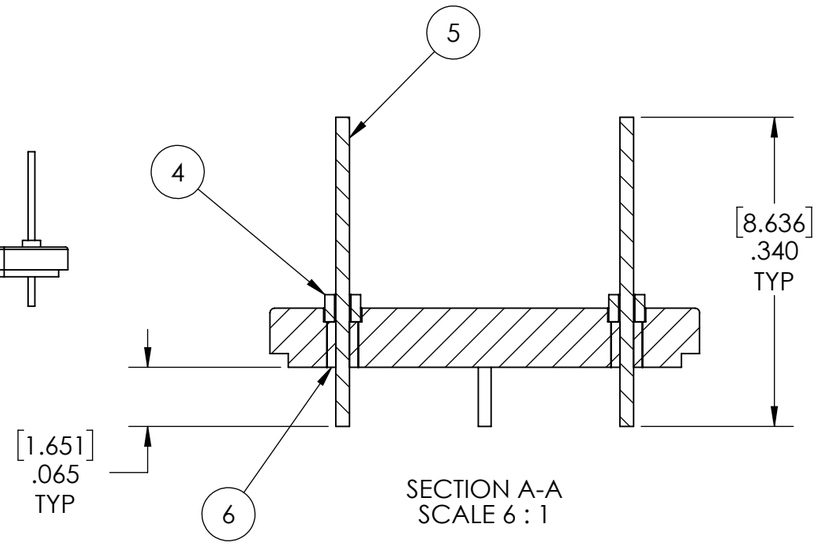
SIZE	DWG. NO.	REV
B	6005	1.0

SCALE: 16:1 SHEET 1 OF 1

REVISIONS				
REV.	ECO	DESCRIPTION	DRAWN BY	DATE







SECTION A-A
SCALE 6 : 1

NOTES:
UNLESS OTHERWISE SPECIFIED:

1. FEEDTHROUGH SHALL UNDERGO THERMAL CYCLING TO MIL-STD-883, METHOD 1010.9, TEST CONDITION B (MINUS 55C TO PLUS 125 C, OR 10 CYCLES AT 15 MINUTE DWELLS). THIS INCLUDES TEMPERATURE TRANSITIONS FEEDTHROUGH SHALL HAVE A LEAK RATE LESS THN 5X10^-9 ATM CC/SEC FOR THERMAL SHOCK SPECIFIED IN MIL-STD-883, METHOD 1011.9, SECTION 3.1, TIMING.
2. FEEDTHROUGH SHALL MEET VISUAL CRITERIA OF HERMETIC SOLUTIONS GROUP WORKMANSHIP QUALITY STANDARD WQS-102. FOR THE MINIMUM ACCEPTABLE QUALITY LEVEL FOR KRYOFLEX CERAMIC SEALS.
3. FEEDTHROUGH PIN TO PIN TO FLANGE INSULATION RESISTANCE SHALL BE 50 MEGA OHM MINIMUM WHEN TESTED IN ACCORDANCE WITH MIL-STD-202, METHOD 302, TEST CONDITION A (100 VDC).
4. MATERIAL CERTIFICATION FILES WITH TRACEABILITY FOR ALL MATERIALS USED IN PRODUCT AND PROCESS(E.G., TO BE KEPT IN VENDOR FILES FOR A MINIMUM OF 15 YEARS, OR ACCORDING TO VENDOR REQUIREMENTS.
5. FINAL INSPECTION AND TEST RESULTS FOR EACH PART SHALL BE KEPT IN VENDOR FILES FOR A MINIMUM OF 15 YEARS, OR ACCORDING TO VENDOR REQUIREMENTS.
6. A CERTIFICATE OF CONFORMANCE SHALL ACCOMPANY ALL DELIVERIES VERIFYING PARTS MET ALL DRAWING REQUIREMENTS AND REQUIRED RECORDS ARE ON FILE. RECORDS SHALL BE PROVIDED TO MED-ALLY UPON REQUEST

ITEM NO.	PART NUMBER	DESCRIPTION	QTY.
1	8164	GROUND PIN	1
2	6164	12 MM LIDTHROUGH PLATE	1
3	XXXX	STRAIGHT ANTENNA WIRE	1
4	XXXX	CAP BEAD	17
5	XXXX	FEEDTHROUGH WIRE	16
6	XXXX	FEEDTHROUGH BRAZE	17

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN [MM] / INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ±0.5 DEG BEND ±
TWO PLACE DECIMAL ±[0.2] / .008
THREE PLACE DECIMAL ±[0.1] / .004

DO NOT SCALE DRAWING

PROPRIETARY AND CONFIDENTIAL

NEXT ASSEMBLY

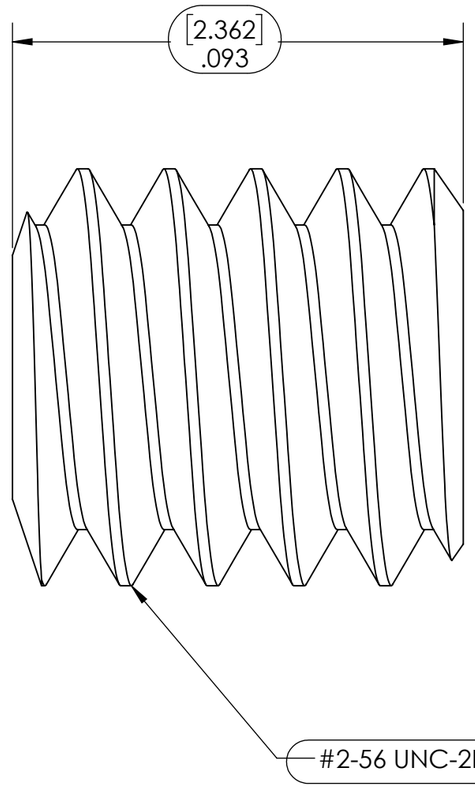
MED-ALLY LLC

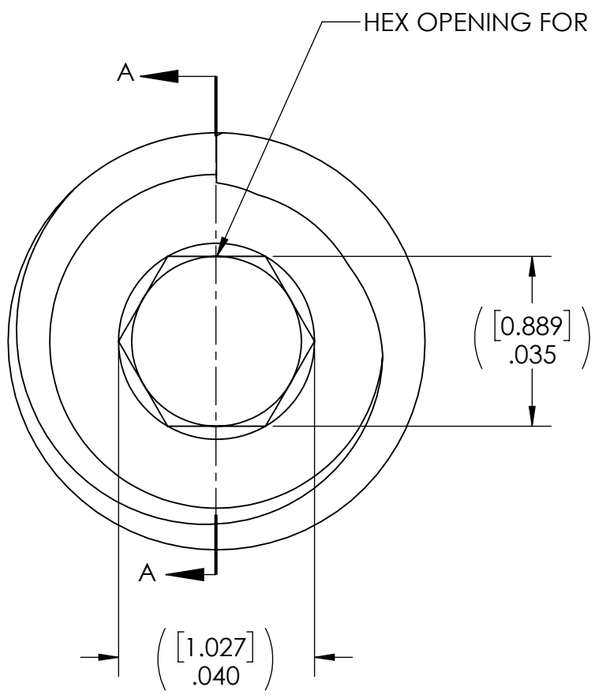
TITLE:
12 MM LIDTHROUGH ASSEMBLY

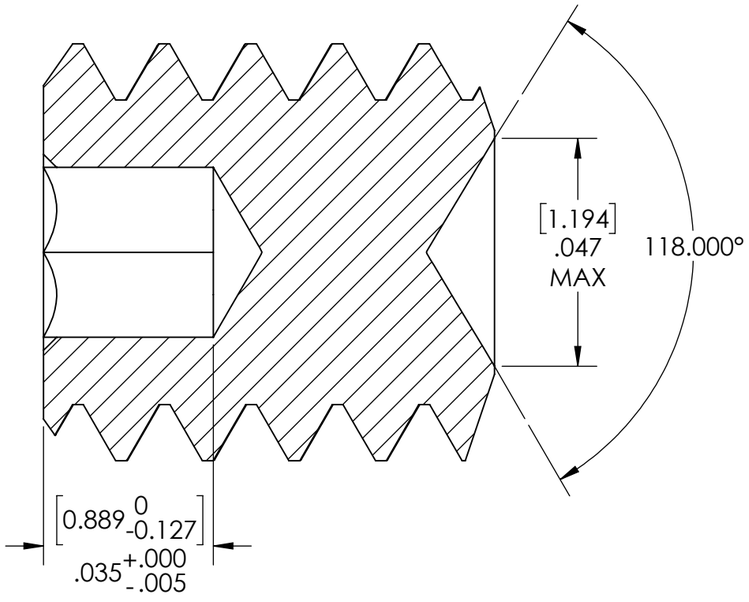
SIZE	DWG. NO.	REV
B	5034	0.2

SCALE: 2:1 SHEET 1 OF 1

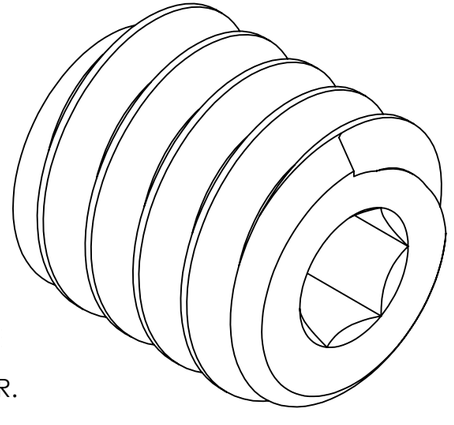
REVISIONS				
REV.	ECO	DESCRIPTION	DRAWN BY	DATE
1.0	19-59	INITIAL RELEASE	S. BEHAN	11/26/19







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: DIMENSIONS ARE IN MM TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±.5 BEND ± TWO PLACE DECIMAL ±0.20 THREE PLACE DECIMAL ±0.10 DO NOT SCALE DRAWING	MED-ALLY TITLE: #2-56 SETSCREW
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. 6003 · REV 1.0 SCALE: 32:1 · SHEET 1 OF 1

MED - ALLY	**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.

avantor | NuSil

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 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.

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

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.

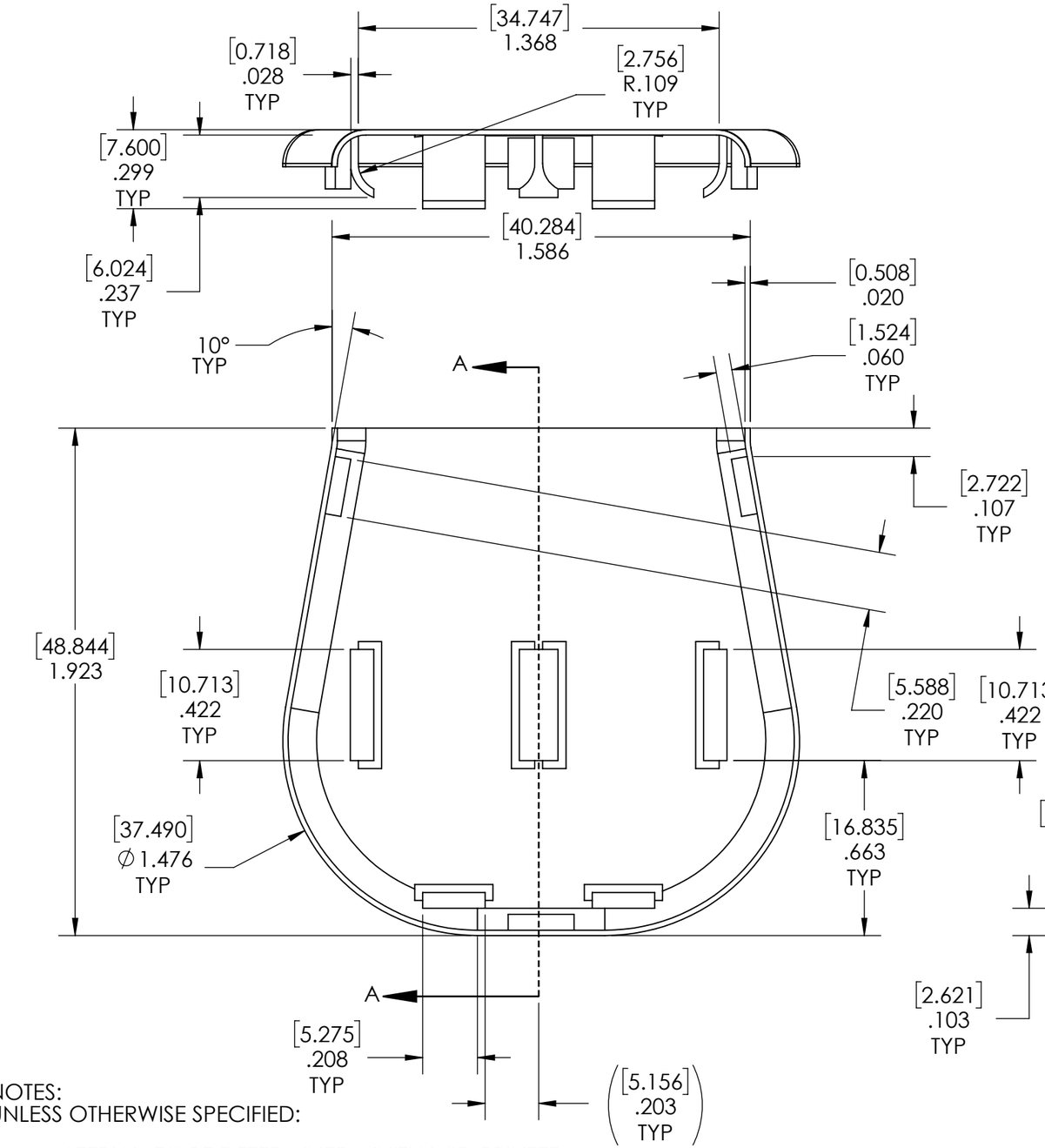
NuSil Technology has tested this material only to determine if the product meets the applicable specifications. (Please contact NuSil Technology for assistance and recommendations when establishing specifications.) When considering the use of NuSil Technology products in a particular application, review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

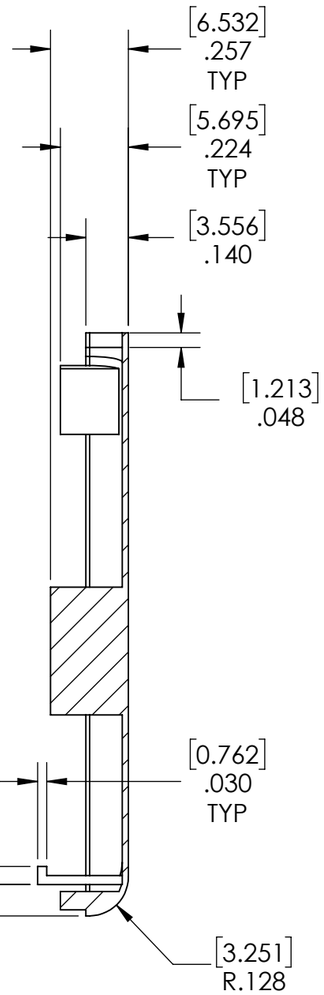
Do not use any chemical in a food, drug, cosmetic, or medical application or process until having determined the safety and legality of the use. The user is responsible to meet the requirements of the U.S. Food and Drug Administration (FDA) and any other regulatory agencies. Before handling any other 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.

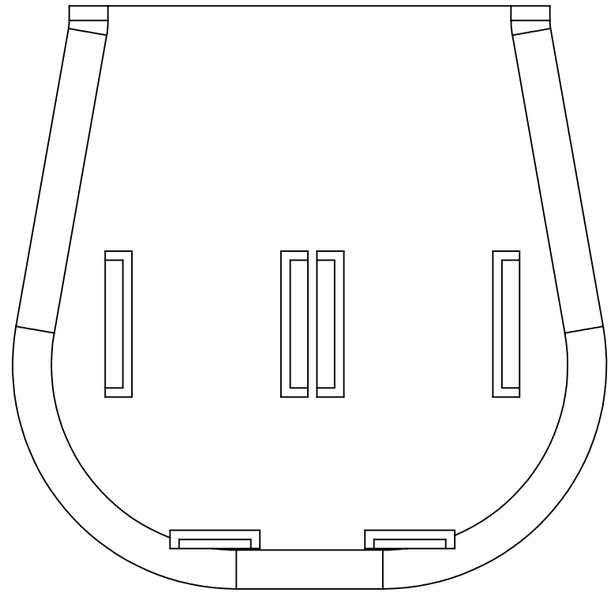
PATENT / INTELLECTUAL PROPERTY WARNING

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







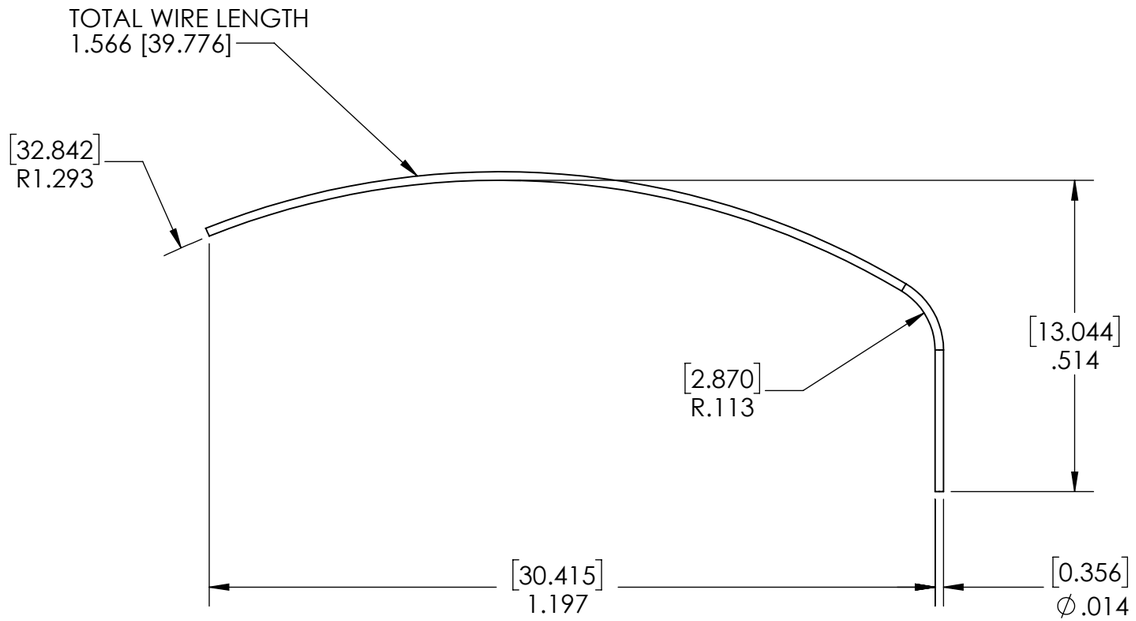
SECTION A-A

NOTES:
UNLESS OTHERWISE SPECIFIED:

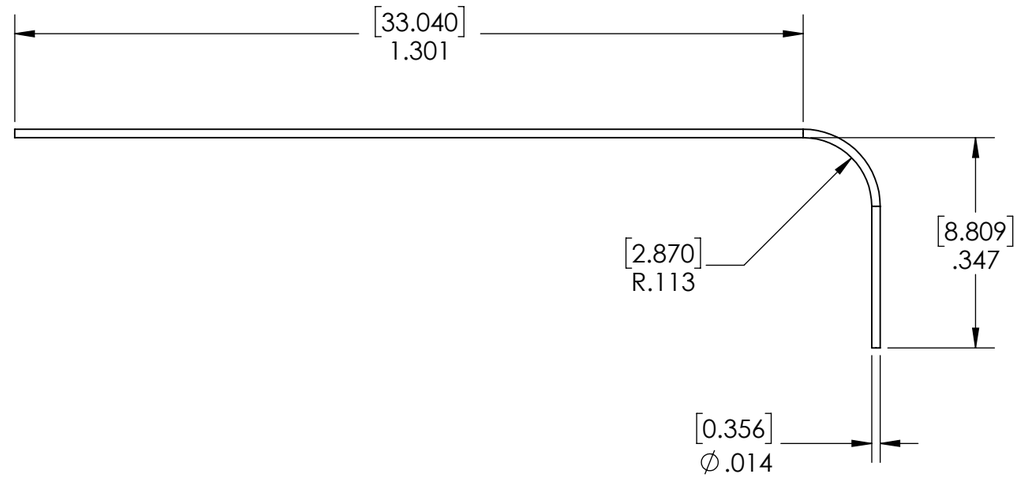
1. MATERIAL: TO BE DETERMINED. (INITIAL 3D PRINTED.)
2. DIMENSIONAL VERIFICATION METHODS TO BE DETERMINED BETWEEN CUSTOMER AND SUPPLIER.
3. PARTS ARE TO BE CLEAN AND FREE OF DIRT, GREASE AND OTHER PROCESS CONTAMINATES.
4. VENDOR SHALL SUPPLY MATERIAL CERTIFICATIONS WITH MATERIAL LOT NUMBERS USED IN FABRICATION OF PARTS.

UNLESS OTHERWISE SPECIFIED:	MED-ALLY LLC
DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±0.5 DEG BEND ± TWO PLACE DECIMAL ±[0.2] / .008 THREE PLACE DECIMAL ±[0.1] / .004 DO NOT SCALE DRAWING	TITLE: BOTTOM NEST
PROPRIETARY AND CONFIDENTIAL THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY LLC. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF, MED-ALLY LLC, IS PROHIBITED.	SIZE B · DWG. NO. XXXXX · REV B SCALE: 2:1 · SHEET 1 OF 1
NEXT ASSEMBLY	

REVISIONS				
REV.	ECO	DESCRIPTION	DRAWN BY	DATE



FINAL FORMED CONFIGURATION



SHIPPING CONFIGURATION

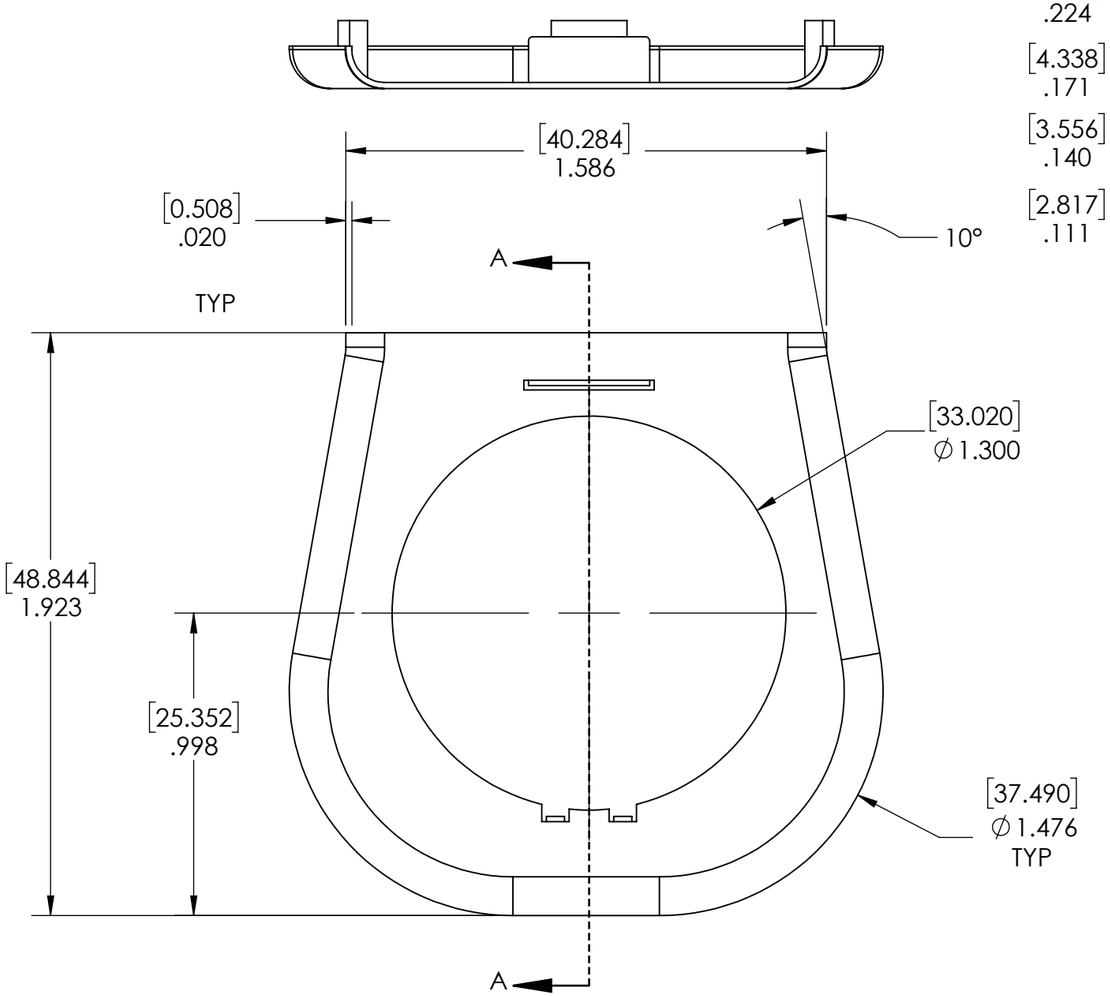
NOTES:
UNLESS OTHERWISE SPECIFIED:

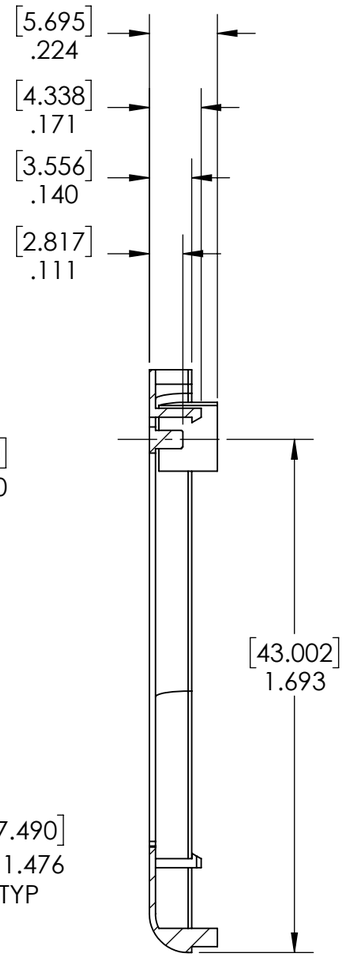
1. MATERIAL: 90% Pt/10% Ir PER ASTM B265.

NEXT ASSEMBLY

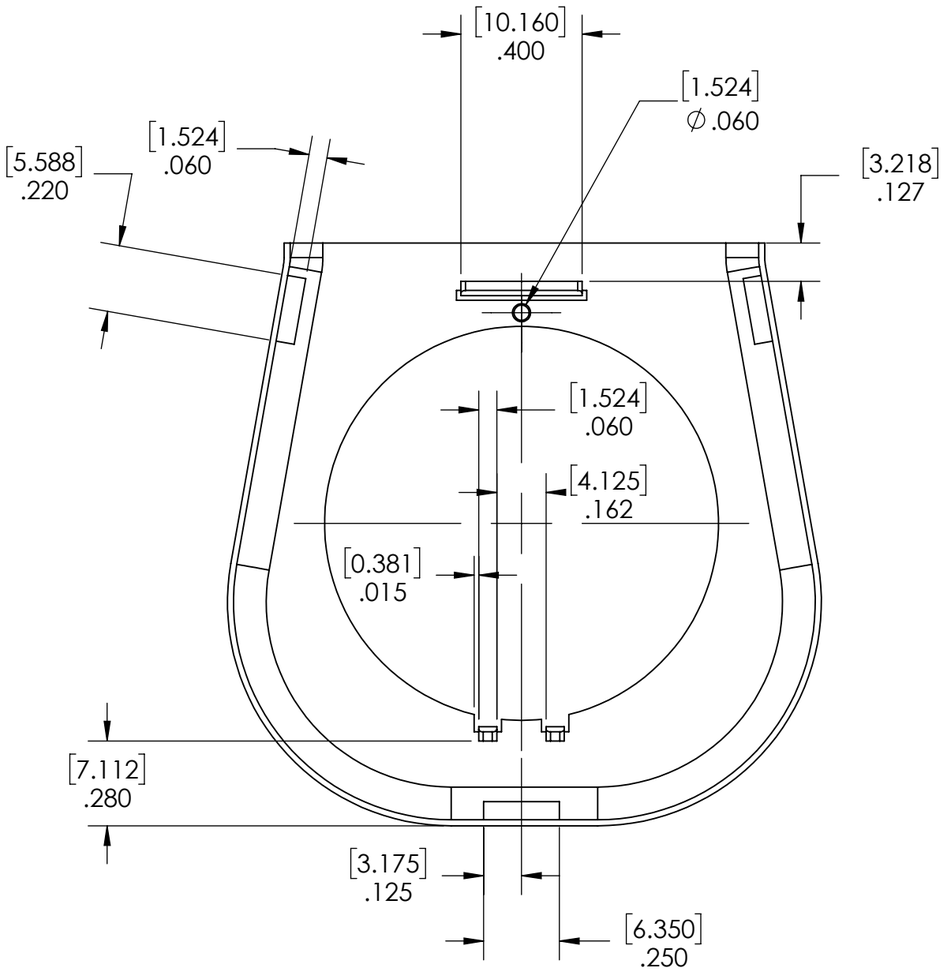
UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN [MM] / INCHES TOLERANCES: FRACTIONAL ± ANGULAR: MACH ±0.5 DEG BEND ± TWO PLACE DECIMAL ±[0.2] / .008 THREE PLACE DECIMAL ±[0.1] / .004 DO NOT SCALE DRAWING	MED-ALLY LLC TITLE: ANTENNA WIRE
PROPRIETARY AND CONFIDENTIAL THE INFORMATION CONTAINED IN THIS DRAWING IS THE SOLE PROPERTY OF MED-ALLY LLC. ANY REPRODUCTION IN PART OR AS A WHOLE WITHOUT THE WRITTEN PERMISSION OF, MED-ALLY LLC, IS PROHIBITED.	SIZE B · DWG. NO. XXXX · REV 0.1 SCALE: 5:1 · SHEET 1 OF 1

REVISIONS				
REV.	ECO	DESCRIPTION	DRAWN BY	DATE





SECTION A-A



NOTES:
UNLESS OTHERWISE SPECIFIED:

1. MATERIAL: TO BE DETERMINED. (INITIAL 3D PRINTED.)
2. DIMENSIONAL VERIFICATION METHODS TO BE DETERMINED BETWEEN CUSTOMER AND SUPPLIER.
3. PARTS ARE TO BE CLEAN AND FREE OF DIRT, GREASE AND OTHER PROCESS CONTAMINATES.
4. VENDOR SHALL SUPPLY MATERIAL CERTIFICATIONS WITH MATERIAL LOT NUMBERS USED IN FABRICATION OF PARTS.

NEXT ASSEMBLY

UNLESS OTHERWISE SPECIFIED:

DIMENSIONS ARE IN [MM] / INCHES
TOLERANCES:
FRACTIONAL ±
ANGULAR: MACH ±0.5 DEG BEND ±
TWO PLACE DECIMAL ±[0.2] / .008
THREE PLACE DECIMAL ±[0.1] / .004

DO NOT SCALE DRAWING

MED-ALLY LLC

TITLE:

TOP NEST

SIZE	DWG. NO.	REV
B	XXXXX	A
SCALE: 2:1		SHEET 1 OF 1