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(12) **United States Design Patent** (10) **Patent No.: US D1,033,641 S**
Morelock (45) **Date of Patent: ** Jul. 2, 2024**

(54) **MICRONEEDLE ARRAY SENSOR APPLICATOR DEVICE**

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(73) Assignee: **Biolinq Incorporated**, San Diego, CA (US)

(**) Term: **15 Years**

(21) Appl. No.: **29/819,952**

(22) Filed: **Dec. 17, 2021**

(51) **LOC (14) Cl.** **24-02**

(52) **U.S. Cl.**
USPC **D24/146**

(58) **Field of Classification Search**
USPC D24/107, 108, 112, 130, 133, 146, 147, D24/186; D15/72, 78; D28/7; D9/772, D9/773, 774, 777
CPC A61M 37/0015; A61M 2037/0038; A61M 2037/0053; A61M 2037/003; A61M 2037/0023; A61M 2037/0061; A61M 2207/00; A61M 2037/0046; A61N 1/328; A61B 5/145; A61B 5/14503
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

D178,118	S *	6/1956	Enos	D15/72
D315,914	S *	4/1991	Chen	D15/78
D438,794	S *	3/2001	Miles	D9/425
D444,594	S *	7/2001	Angeletta	D28/7
6,855,131	B2	2/2005	Trautman et al.	
7,097,631	B2	8/2006	Trautman et al.	
D544,298	S *	6/2007	Eide	D7/565
7,582,059	B2	9/2009	Funderburk et al.	
7,946,984	B2	5/2011	Brister et al.	
8,094,009	B2	1/2012	Allen et al.	
8,125,331	B2	2/2012	Allen et al.	
8,130,095	B2	3/2012	Allen et al.	
8,175,673	B2	5/2012	Say et al.	

(Continued)

FOREIGN PATENT DOCUMENTS

AU	2015227515 B2	5/2017
EP	2 532 305 A1	12/2012

(Continued)

OTHER PUBLICATIONS

Freestyle Libre 3 Sensor, usmeddirect.com, [online], [site visited Sep. 21, 2023], Available from internet, URL: https://www.usmeddirect.com/products/freestyle-libre-3-sensor-prescription-required (Year: 2023).*

(Continued)

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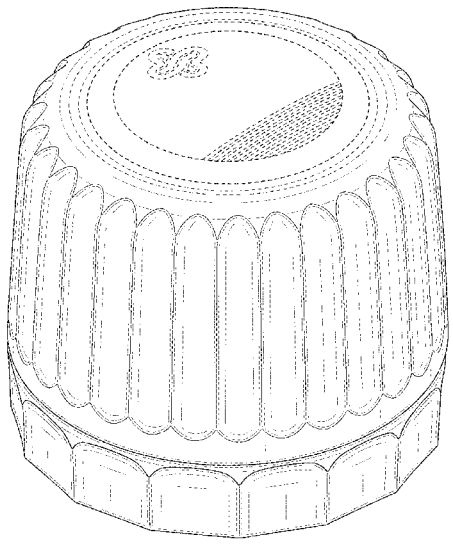
(57) **CLAIM**

The ornamental design for a microneedle array sensor applicator device, as shown and described.

DESCRIPTION

FIG. **1** is a front perspective view of a microneedle array sensor applicator device showing the new design;
FIG. **2** is a front view thereof;
FIG. **3** is a right side view thereof;
FIG. **4** is a rear view thereof;
FIG. **5** is a left side view thereof;
FIG. **6** is a top plan view thereof; and,
FIG. **7** is a bottom plan view thereof.
The broken lines illustrate portions of the microneedle array sensor applicator device that form no part of the claimed design.

1 Claim, 7 Drawing Sheets



(56) **References Cited**

U.S. PATENT DOCUMENTS

8,252,229 B2 8/2012 Thomas et al.
8,267,889 B2 9/2012 Cantor et al.
8,280,475 B2 10/2012 Brister et al.
8,284,046 B2 10/2012 Allen et al.
D681,877 S * 5/2013 Curry D28/7
8,579,862 B2 11/2013 Kobayashi et al.
8,652,043 B2 2/2014 Drucker et al.
8,753,318 B2 6/2014 Trautman et al.
8,758,298 B2 6/2014 Cantor et al.
8,764,657 B2 7/2014 Curry et al.
8,821,446 B2 9/2014 Trautman et al.
D717,100 S * 11/2014 Moser D7/354
9,008,745 B2 4/2015 Pushpala et al.
9,055,901 B2 6/2015 Brister et al.
9,101,305 B2 8/2015 Larson et al.
9,119,945 B2 9/2015 Simons et al.
9,174,035 B2 11/2015 Ringsred et al.
9,215,992 B2 12/2015 Donnay et al.
9,357,951 B2 6/2016 Simpson et al.
9,402,544 B2 8/2016 Yee et al.
9,402,570 B2 8/2016 Pace et al.
9,415,198 B2 8/2016 McAllister
9,492,647 B2 11/2016 Stumber et al.
9,610,401 B2 4/2017 Antonio et al.
9,615,779 B2 4/2017 Pryor et al.
9,636,060 B2 5/2017 Feldman et al.
9,642,568 B2 5/2017 Shah et al.
9,687,640 B2 6/2017 Trautman et al.
9,717,843 B2 8/2017 Grucela et al.
9,737,247 B2 8/2017 Wang et al.
9,743,870 B2 8/2017 Wang et al.
9,782,574 B2 10/2017 Simmers
9,789,249 B2 10/2017 Frederickson et al.
9,814,414 B2 11/2017 Brister et al.
D806,254 S * 12/2017 Im D24/186
9,844,328 B2 12/2017 Simpson et al.
9,933,387 B1 4/2018 McCanna et al.
9,949,642 B2 4/2018 Love et al.
9,968,742 B2 5/2018 Van Antwerp et al.
10,010,280 B2 7/2018 Donnay et al.
10,010,707 B2 7/2018 Colburn et al.
D827,682 S * 9/2018 Anderson 15/78
10,092,207 B1 10/2018 Windmiller
10,136,846 B2 11/2018 Wang et al.
10,213,139 B2 2/2019 Rao et al.
10,213,141 B2 2/2019 Cole et al.
10,278,732 B2 5/2019 Schoonmaker et al.
10,300,260 B2 5/2019 Wirtanen et al.
10,406,339 B2 9/2019 Simmers
10,413,183 B2 9/2019 Antonio et al.
10,492,685 B2 12/2019 Bernstein et al.
10,492,708 B1 12/2019 Windmiller
D875,254 S 2/2020 Cooke et al.
10,595,754 B2 3/2020 Pushpala et al.
10,596,295 B2 3/2020 Larson et al.
10,674,944 B2 6/2020 Pace
10,709,834 B2 7/2020 Chiu et al.
10,863,944 B2 12/2020 Gray et al.
10,898,115 B2 1/2021 Halac et al.
10,932,699 B2 3/2021 Lin et al.
10,973,443 B2 4/2021 Funderburk et al.
10,993,646 B2 5/2021 Scott et al.
11,045,142 B1 6/2021 Windmiller et al.
D924,406 S * 7/2021 Yee D24/186
11,058,329 B2 7/2021 Simpson et al.
11,071,478 B2 7/2021 Rao et al.
D928,119 S * 8/2021 Walter D14/216
11,122,043 B2 9/2021 Love et al.
11,172,851 B2 11/2021 Pushpala et al.
11,357,430 B2 6/2022 Pushpala et al.
11,406,818 B2 8/2022 Windmiller
11,517,222 B2 12/2022 Pushpala et al.
D980,986 S * 3/2023 Rao A61B 5/14503 D24/186
11,654,270 B2 5/2023 Mansfield et al.
D988,160 S * 6/2023 Morelock D24/186
11,672,965 B2 6/2023 Mansfield et al.
D996,999 S * 8/2023 Morelock D24/186
D997,362 S * 8/2023 Donnay A61B 5/15194 D24/169
D999,913 S * 9/2023 Rao D24/186
D1,006,235 S * 11/2023 Rao D24/186
D1,008,021 S * 12/2023 Jensen D24/130
2002/0087182 A1 7/2002 Trautman et al.
2004/0236251 A1 * 11/2004 Roe A61B 5/150022 600/583
2005/0096586 A1 5/2005 Trautman et al.
2005/0283114 A1 * 12/2005 Bresina A61M 5/158 604/93.01
2008/0114280 A1 5/2008 Stafford
2008/0183144 A1 7/2008 Trautman et al.
2008/0242961 A1 10/2008 Brister et al.
2010/0056873 A1 3/2010 Allen et al.
2011/0082484 A1 4/2011 Saravia et al.
2011/0106126 A1 5/2011 Love et al.
2011/0190603 A1 8/2011 Stafford
2011/0191044 A1 * 8/2011 Stafford C12Q 1/006 702/65
2011/0319729 A1 12/2011 Donnay et al.
2012/0123387 A1 5/2012 Gonzalez et al.
2012/0197222 A1 8/2012 Donnay et al.
2012/0303043 A1 * 11/2012 Donnay A61B 5/6849 606/129
2014/0275907 A1 9/2014 Feldman et al.
2014/0330209 A1 11/2014 Frederickson et al.
2014/0336487 A1 11/2014 Wang et al.
2015/0173661 A1 6/2015 Myles
2015/0351674 A1 12/2015 Thomas et al.
2016/0029931 A1 2/2016 Salas-Boni et al.
2017/0361079 A1 12/2017 Trautman et al.
2018/0317820 A1 11/2018 Pace et al.
2019/0059796 A1 2/2019 Larson et al.
2019/0120785 A1 4/2019 Halac et al.
2019/0125223 A1 5/2019 Wang et al.
2019/0133501 A1 5/2019 Rao et al.
2019/0133510 A1 5/2019 El Kaliouby et al.
2019/0239825 A1 8/2019 Kumar et al.
2019/0309433 A1 10/2019 Sattayasamitsathit et al.
2019/0336053 A1 11/2019 Halac et al.
2019/0339224 A1 11/2019 Bhavaraju et al.
2020/0037939 A1 2/2020 Castagna et al.
2020/0085341 A1 3/2020 Windmiller
2020/0101286 A1 4/2020 Windmiller et al.
2020/0138346 A1 5/2020 Brister et al.
2020/0178853 A1 6/2020 Pushpala et al.
2020/0209179 A1 7/2020 Bohm et al.
2020/0214566 A1 7/2020 Allen et al.
2020/0254240 A1 8/2020 Windmiller et al.
2020/0297997 A1 9/2020 Windmiller et al.
2020/0330010 A1 10/2020 Barry et al.
2020/0375455 A1 12/2020 Van Tassel et al.
2021/0000399 A1 1/2021 Curry et al.
2021/0007651 A1 1/2021 Donnay et al.
2021/0038131 A1 2/2021 Li et al.
2021/0076987 A1 3/2021 Stafford
2021/0133126 A1 5/2021 Yamakita et al.
2021/0142912 A1 5/2021 Belliveau et al.
2021/0186425 A1 6/2021 Rodriguez et al.
2021/0187286 A1 6/2021 Windmiller et al.
2021/0196162 A1 7/2021 Halac et al.
2021/0204841 A1 7/2021 Thomas et al.
2021/0219877 A1 7/2021 Baker et al.
2021/0236057 A1 8/2021 Pushpala et al.
2021/0260257 A1 8/2021 McCanless et al.
2021/0308009 A1 10/2021 Cho et al.
2021/0315493 A1 10/2021 Pace et al.
2021/0321914 A1 10/2021 Brister et al.
2021/0321942 A1 10/2021 Pushpala et al.
2021/0379370 A1 12/2021 Windmiller
2021/0393201 A1 12/2021 Morelock et al.
2022/0031209 A1 2/2022 Windmiller et al.
2022/0031244 A1 2/2022 Windmiller et al.
2022/0079481 A1 3/2022 Pushpala et al.
2022/0080678 A1 3/2022 Cole et al.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2022/0087610	A1	3/2022	Pushpala et al.
2022/0125344	A1	4/2022	Pushpala et al.
2022/0151516	A1	5/2022	Wang et al.
2022/0175278	A1	6/2022	Campbell et al.
2022/0370011	A1	11/2022	Windmiller et al.
2023/0033467	A1	2/2023	Pushpala et al.
2023/0074798	A1	3/2023	Tangney
2023/0094419	A1	3/2023	Mansfield, III et al.
2023/0099617	A1	3/2023	Mansfield, III et al.
2023/0137258	A1	5/2023	Windmiller
2023/0190147	A1	6/2023	Campbell et al.
2023/0256220	A1	8/2023	Mansfield, III et al.
2023/0301552	A1	9/2023	Mallires et al.
2023/0310823	A1	10/2023	Mansfield, III et al.

FOREIGN PATENT DOCUMENTS

JP	D1707722	*	2/2022
WO	WO-2007/097754	A1	8/2007
WO	WO-2013/066854	A1	5/2013
WO	WO-2014/055456	A1	4/2014
WO	WO-2018/071265	A1	4/2018
WO	WO-2019/084023	A1	5/2019
WO	WO-2019/236859	A1	12/2019
WO	WO-2019/236876	A1	12/2019
WO	WO-2020/231405	A1	11/2020
WO	WO-2021/101857	A1	5/2021
WO	WO-2021/158372	A1	8/2021
WO	WO-2021/257624	A1	12/2021
WO	WO-2023/055755	A1	4/2023
WO	WO-2023/064877	A1	4/2023
WO	WO-2023/133468	A1	7/2023

OTHER PUBLICATIONS

Dexcom G7 Sensor, pharmalynk.com, [online], [site visited Sep. 21, 2023], Available from internet, URL: https://store.pharmalynk.com/products/dexcom-g7-cgm (Year: 2023).*

Abbot press release (2020). "New late-breaking data show use of Abbott's Freestyle® Libre System significantly reduces HBA1C levels in people with type 2 diabetes using insulin or not," 3 pages.

American Diabetes Association® Press Release (2020). "American Diabetes Association® Applauds policymakers' Focus on Addressing High Costs of Insulin for Seven Million Americans," 4 pages.

Bantle, J.P. et al. (1997). "Glucose measurement in patients with diabetes mellitus with dermal interstitial fluid," J. Lab. Clin. Med. 130:436-441.

Beckles, G.L. et al. (2016). "Disparities in the prevalence of diagnosed diabetes—United States, 1999-2002 and 2011-2014," MMWR 65:1265-1269.

Cao, J. et al. (2017). "Validation of capillary blood analysis and capillary testing mode on the epoc Point of Care system," Pract. Lab. Med. 9:24-27.

Castle, J.R. et al. (2012). "The accuracy benefit of multiple amperometric glucose sensors in people with type 1 diabetes," Diabetes Care 35:706-710.

Dexcom (2020). Analyst Day Presentation, 19 total pages.

Dexcom (2020). Analyst Day Presentation, 27 total pages.

Diabetes Care (2021). "7. Diabetes Technology: Standards of Medical Care in Diabetes—2021," Diabetes Care 44(Supplement 1):S85-S99.

Fang, M. et al. (2021). "Trends in Diabetes Treatment and Control in U.S. Adults, 1999-2018," N. Engl. Med. 384:2219-2228.

French, D.P. et al. (2008). "Original Article: Psychological Care Self-monitoring of blood glucose changed non-insulin-treated Type 2 diabetes patients' beliefs about diabetes and self-monitoring in a randomized trial," Diav. Med. 25:1218-1228.

Grady, M. et al. (2017). "Examining the Impact of a Novel Blood Glucose Monitor with Color Range indicator on Decision-Making in Patients With Type 1 and Type 2 Diabetes and its Association With Patient Numeracy Level," JMIR Diabetes 2:e24.

Grady, M. et al. (2018). "Use of Blood Glucose Meters Featuring Color Range Indicators Improves Glycemic Control in Patients with Diabetes in Comparison to Blood Glucose Meters Without Color (ACCENTS Study)," J. Diab. Scl. Tech. 12:1211-1219.

Groenendaal, W. et al. (2008). "Modeling Glucose and Water Dynamics in Human Skin," Diab. Tech. Therap. 10:283-293.

International Search Report mailed on Sep. 9, 2021, for PCT Application No. PCT/US2021/037511, filed on Jun. 15, 2021, 2 pages.

Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group (2008). "Continuous Glucose Monitoring and Intensive Treatment of Type 1 Diabetes," N. Engl. Med. 359:1464-1476.

Karter, A.J. et al. (2021). "Association of Real-time Continuous Glucose Monitoring with Glycemic Control and Acute Metabolic Events Among Patients with Insulin-Treated Diabetes," JAMA 325:2273-2284.

Martens, T. et al. (2021). "Effect of Continuous Glucose Monitoring on Glycemic Control in Patients with Type 2 Diabetes Treated with Basal Insulin a Randomized Clinical Trial," JAMA 325:2262-2272.

McClatchey, P.M. et al. (2019). "Fibrotic Encapsulation Is the Dominant Source of Continuous Glucose Monitor Delays," Diabetes 68:1892-1901.

Neerken, S. et al. (2004). "Characterization of age-related effects in human skin: A comparative study that applies confocal laser scanning microscopy and optical coherence tomography," J. Biomed. Optics 9:274-281.

Polonsky, W.H. et al. (2011). "A survey of blood glucose monitoring in patients with type 2 diabetes: Are recommendations from health care professionals being followed?" Curr. Med. Res. & Opinion 27:31-37.

Rigla, M. et al. (2018). "Human Subcutaneous Tissue Response to Glucose Sensors: Macrophages Accumulation Impact on Sensor Accuracy," Diabetes Technology & Therapeutics 20:296-302.

Sheikh, Z. et al. (2015). "Macrophages, Foreign Body Giant Cells and Their Response to Implantable Biomaterials," Materials 8:5671-5701.

Shi, T. et al. (2016). "Modeling and Measurement of Correlation between Blood and Interstitial Glucose Changes," J. Diab. Res. vol. 2016, 9 pages.

Written Opinion of the International Searching Authority mailed on Sep. 9, 2021, for PCT Application No. PCT/US2021/037511, filed on Jun. 15, 2021, 6 pages.

Al Hayek et al., "Patient Satisfaction and Clinical Efficacy of Novel Blood Glucose Meters Featuring Color Range Indicators in Patients With Type 2 Diabetes: A Prospective Study" Cureus Oct. 27, 2020; 12(10):e11195. doi: 10.7759/cureus.11195.

Allen et al., "Continuous glucose monitoring counseling improves physical activity behaviors of individuals with type 2 diabetes: A randomized clinical trial" Diabetes Res Clin Pract. (2008) Jun. 80(3): 371-379. doi:10.1016/j.diabres.2008.01.006.

Barrett et al., "Risk for Newly Diagnosed Diabetes >30 Days After SARS-CoV-2 Infection Among Persons Aged <18 Years—United States, Mar. 1, 2020-Jun. 28, 2021" MMWR Morb Mortal Wkly Rep. Jan. 14, 2022; 71(2):59-65. doi: 10.15585/mmwr.mm7102e2.

Centers for Disease Control, "National Diabetes Statistics Report 2020 Estimates of Diabetes and Its Burden in the United States" (2020) 32 pages.

Dunkin et al., "Scarring occurs at a critical depth of skin injury: precise measurement in a graduated dermal scratch in human volunteers" Plast Reconstr Surg. May 2007; 119(6):1722-1732. doi: 10.1097/01.prs.0000258829.07399.f0.

Ehrhardt et al., "Behavior Modification in Prediabetes and Diabetes: Potential Use of Real-Time Continuous Glucose Monitoring " Journal of Diabetes Science and Technology Mar. 2019; 13(2):271-275.

Ehrhardt et al., "The Effect of Real-Time Continuous Glucose Monitoring on Glycemic Control in Patients with Type 2 Diabetes Mellitus" Journal of Diabetes Science and Technology May 2011; 5(3):668-675.

(56) **References Cited**

OTHER PUBLICATIONS

Ehrhardt et al., "Continuous Glucose Monitoring as a Behavior Modification Tool" Clin Diabetes. Apr. 2020;38(2):126-131. doi: 10.2337/cd19-0037.

Fonda et al., "The Cost-Effectiveness of Real-Time Continuous Glucose Monitoring (RT-CGM) in Type 2 Diabetes" Journal of Diabetes Science and Technology (2016) 10(4):898-904.

Han et al., "The End of the Road for the YSI 2300 Analyzer: Where Do We Go Now?" Journal of Diabetes Science and Technology (2020) 14(3):595-600.

Han et al., "The YSI 2300 Analyzer Replacement Meeting Report" Journal of Diabetes Science and Technology (2020) 14(3):679-686.

International Search Report and Written Opinion mailed on Mar. 20, 2023, for PCT Application No. PCT/US2022/044950, filed on Sep. 27, 2022, 26 pages.

International Search Report and Written Opinion mailed on May 22, 2023, for PCT Application No. PCT/US2023/060177, filed on Jan. 5, 2023, 20 pages.

Invitation to Pay Additional Fees mailed on Jan. 26, 2023, for PCT Application No. PCT/US2022/044950, filed on Sep. 27, 2022, 22 pages.

Invitation to Pay Additional Fees mailed on Mar. 28, 2023, for PCT Application No. PCT/US2023/060177, filed on Jan. 5, 2023, 15 pages.

Non-Final Office Action mailed on Apr. 25, 2023, for U.S. Appl. No. 17/348,651, filed Jun. 15, 2021, 24 pages.

Non-Final Office Action mailed on Dec. 7, 2022, for U.S. Appl. No. 17/954,289, filed Sep. 27, 2022, 7 pages.

Non-Final Office Action mailed on Sep. 8, 2023, for U.S. Appl. No. 18/139,308, filed Apr. 25, 2023, 7 pages.

Notice of Allowance mailed on Jan. 26, 2023, for U.S. Appl. No. 17/954,289, filed Sep. 27, 2022, 9 pages.

Notice of Allowance mailed on Jan. 3, 2023, for U.S. Appl. No. 17/954,293, filed Sep. 27, 2022, 8 pages.

Notice of Allowance mailed on Sep. 12, 2023, for U.S. Appl. No. 18/139,302, filed Apr. 25, 2023, 8 pages.

Sharifi et al., "Redundancy in Glucose Sensing: Enhanced Accuracy and Reliability of an Electrochemical Redundant Sensor for Continuous Glucose Monitoring" Journal of Diabetes Science and Technology (2016) 10(3):669-678.

Turner et al., "Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33)" The Lancet Sep. 1998; 352(9131):837-853.

Vigersky et al., "Short- and Long-Term Effects of Real-Time Continuous Glucose Monitoring in Patients with Type 2 Diabetes" Diabetes Care Jan. 2012; 35:32-38.

Wolicki et al., "Epidemiology and Prevention of Vaccine-Preventable Diseases: Chapter 6: Vaccine Administration" Centers for Disease Control and Prevention (2021) 17 pages.

World Health Organization, "Diabetes", Sep. 16, 2022, 5 pages.

Written Opinion (Second Opinion) of the International Preliminary Examining Authority mailed on May 25, 2023, for PCT Application No. PCT/US2022/044950, filed on Sep. 27, 2022, 14 pages.

Young et al., "Glucose Self-monitoring in Non-Insulin-Treated Patients with Type 2 Diabetes in Primary Care Settings: A Randomized Trial" JAMA Intern Med. Jul. 2017; 177(7):920-929.

* cited by examiner

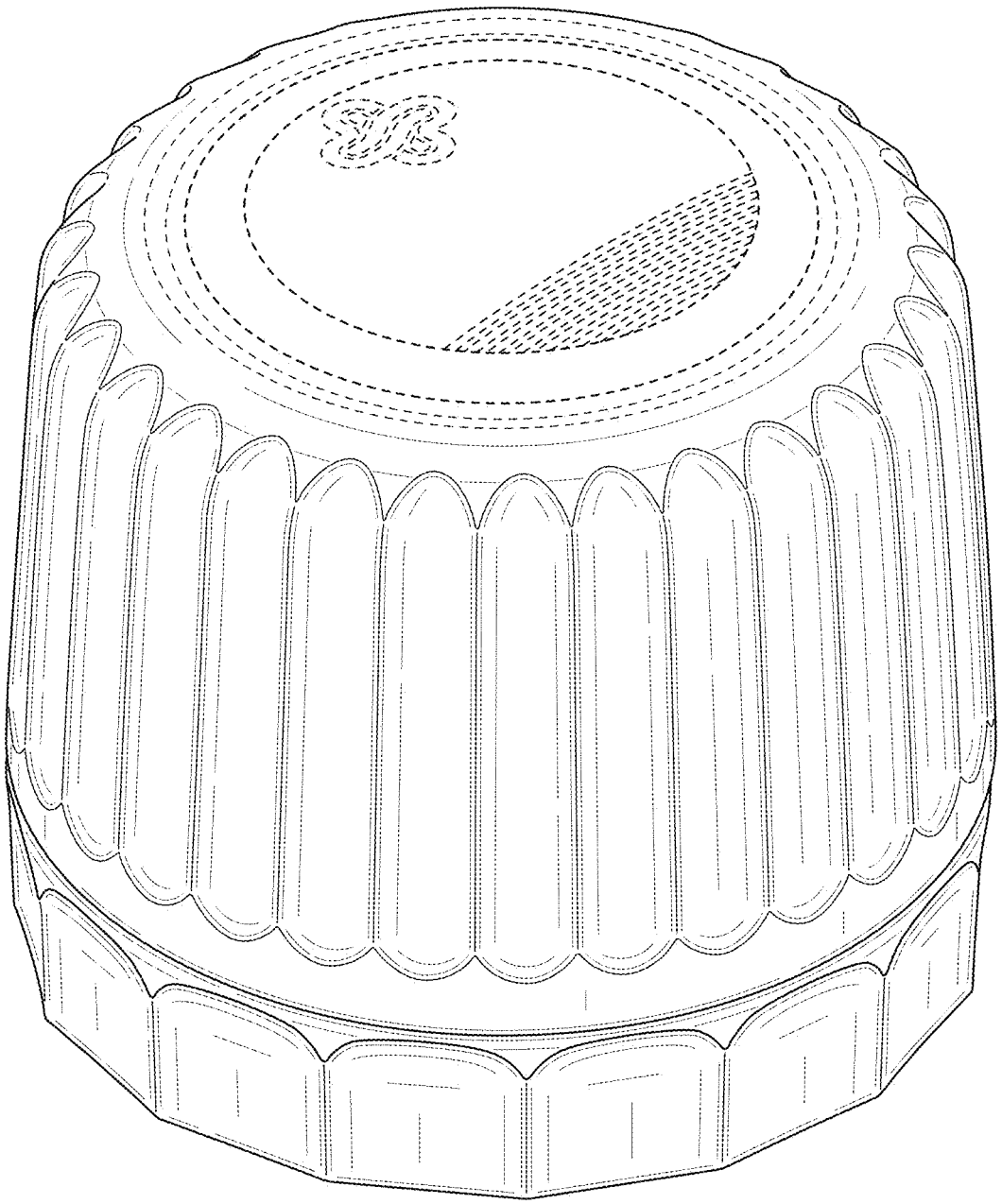


FIG. 1

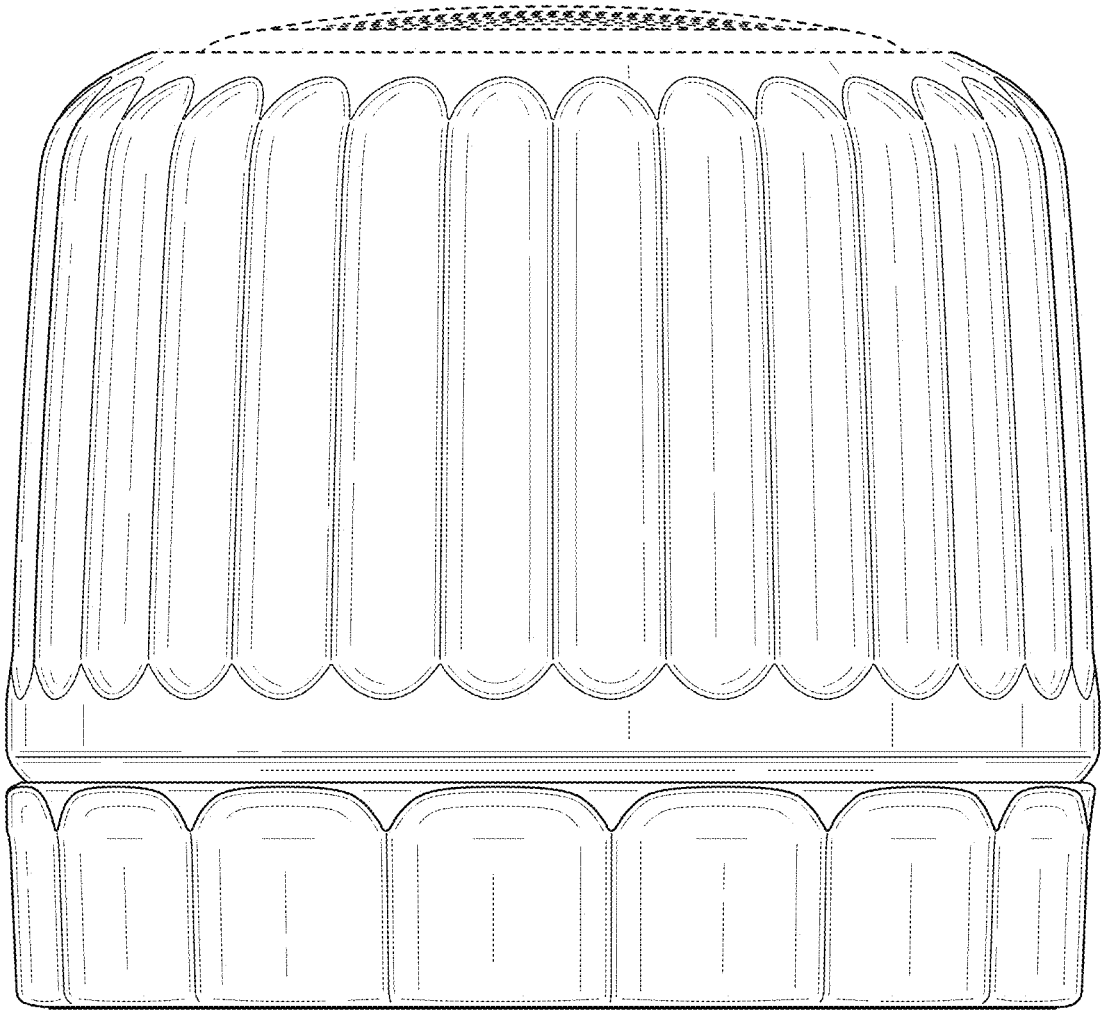


FIG. 2

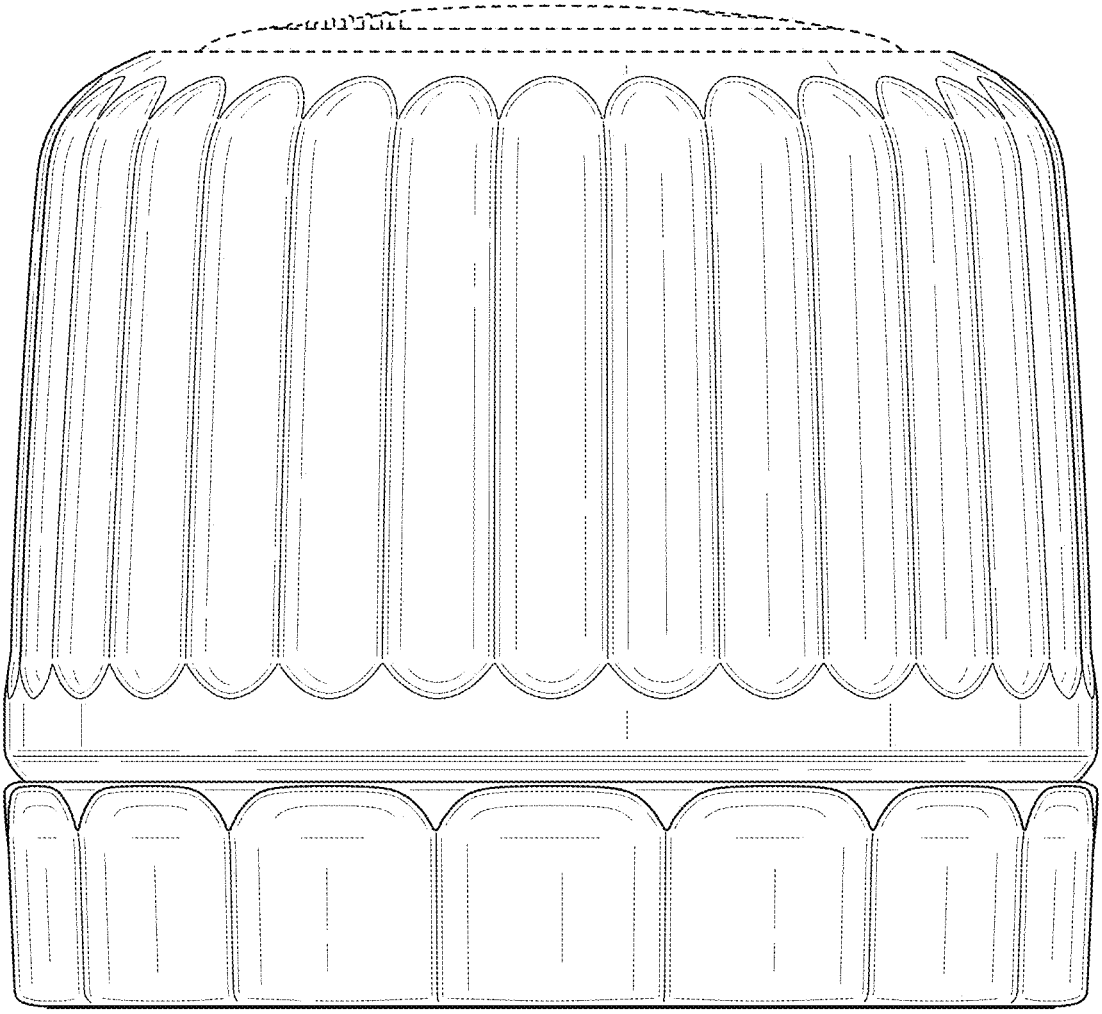


FIG. 3

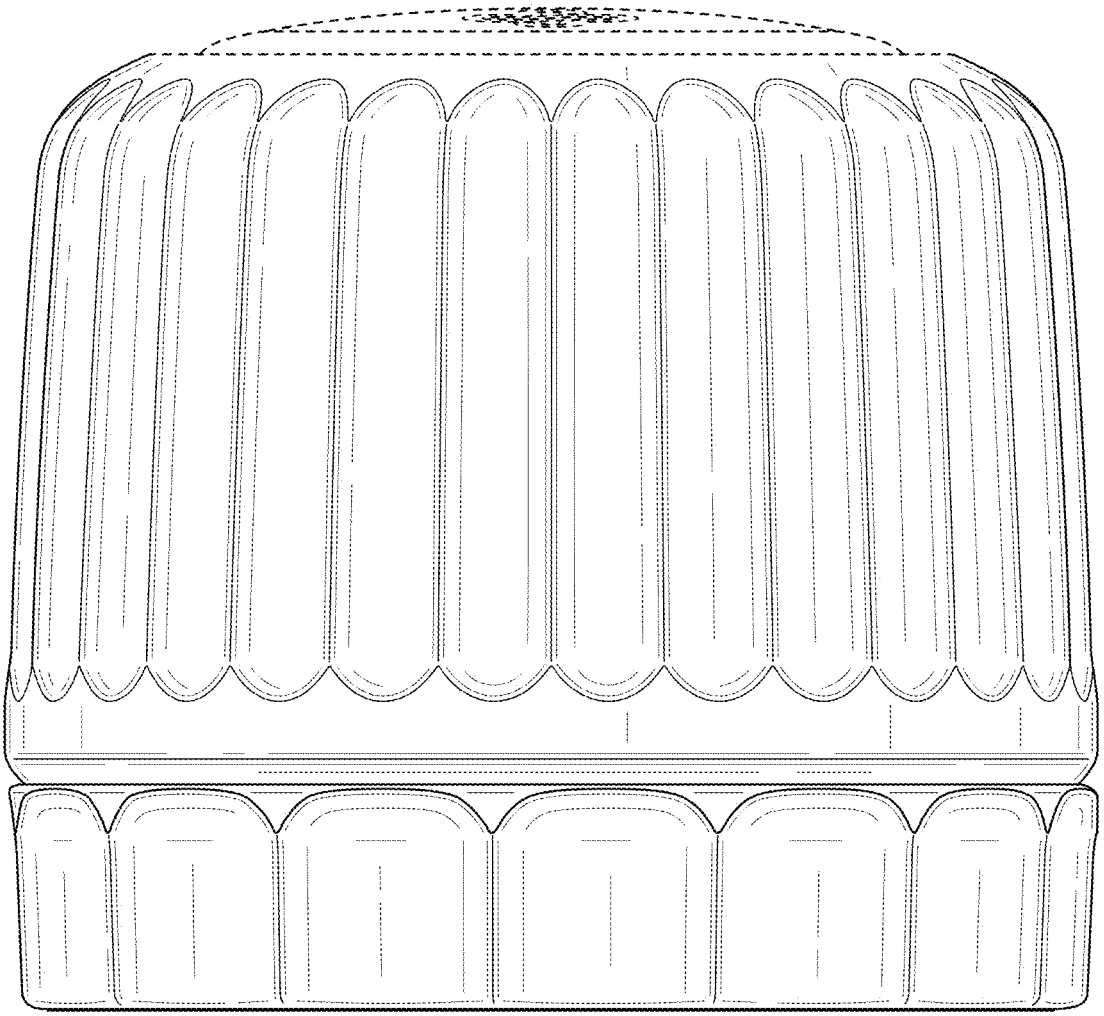


FIG. 4

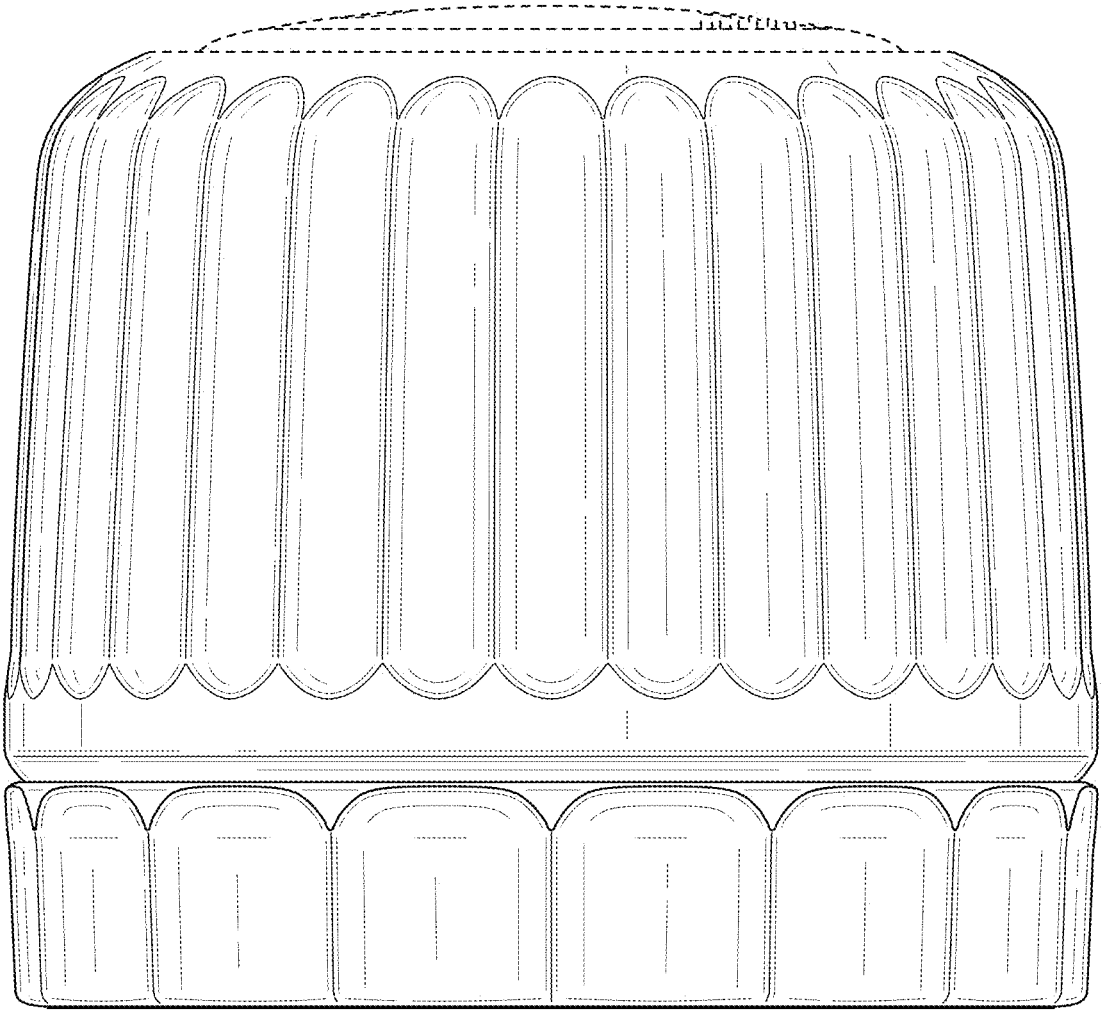


FIG. 5

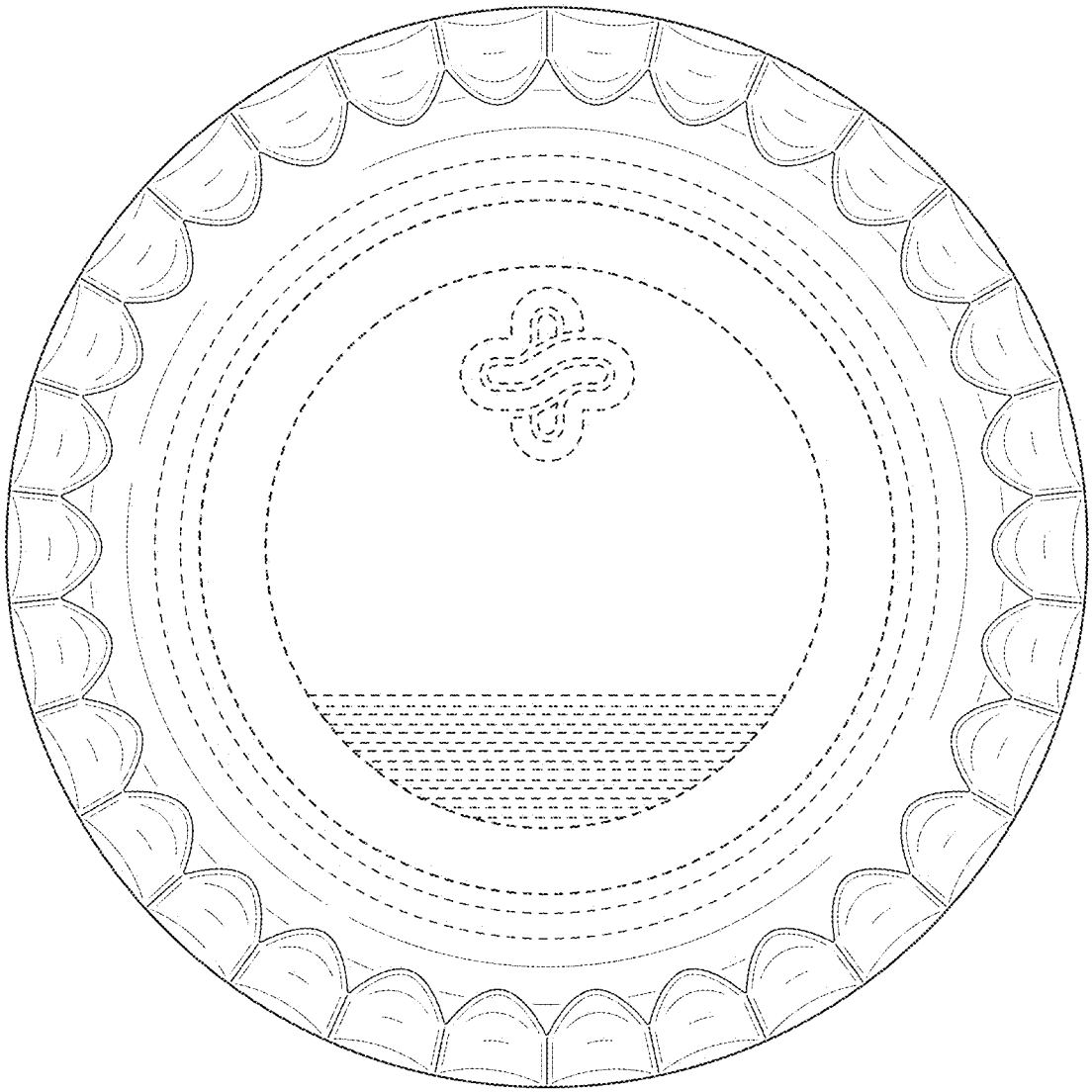


FIG. 6

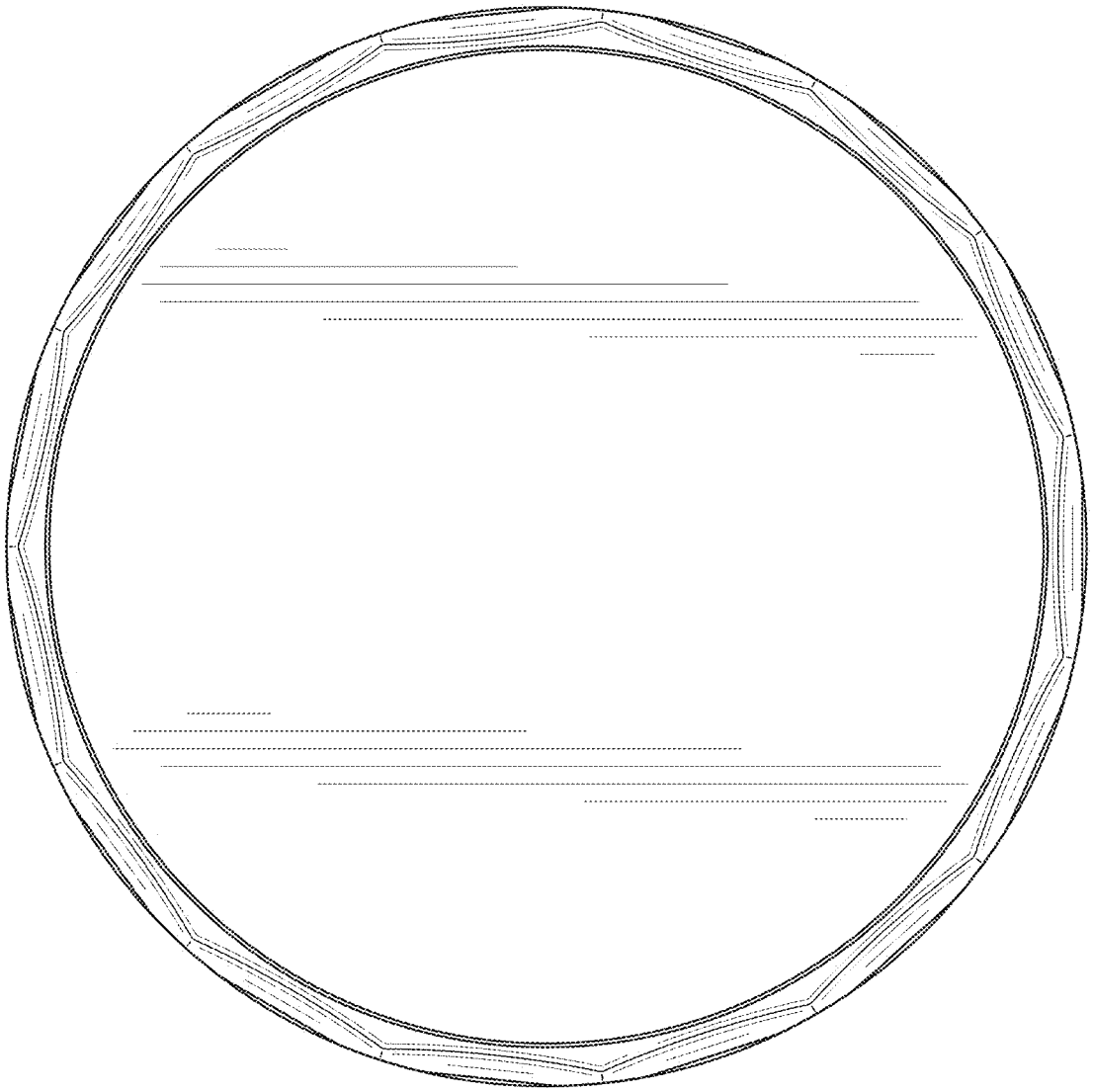


FIG. 7