



US00D861903S

(12) **United States Design Patent**  
**Cryan et al.**

(10) **Patent No.:** **US D861,903 S**

(45) **Date of Patent:** **\*\* Oct. 1, 2019**

(54) **APPARATUS FOR TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION**

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

(21) Appl. No.: **29/647,747**

(22) Filed: **May 15, 2018**

(51) **LOC (12) Cl.** ..... **28-03**

(52) **U.S. Cl.**  
USPC ..... **D24/200**

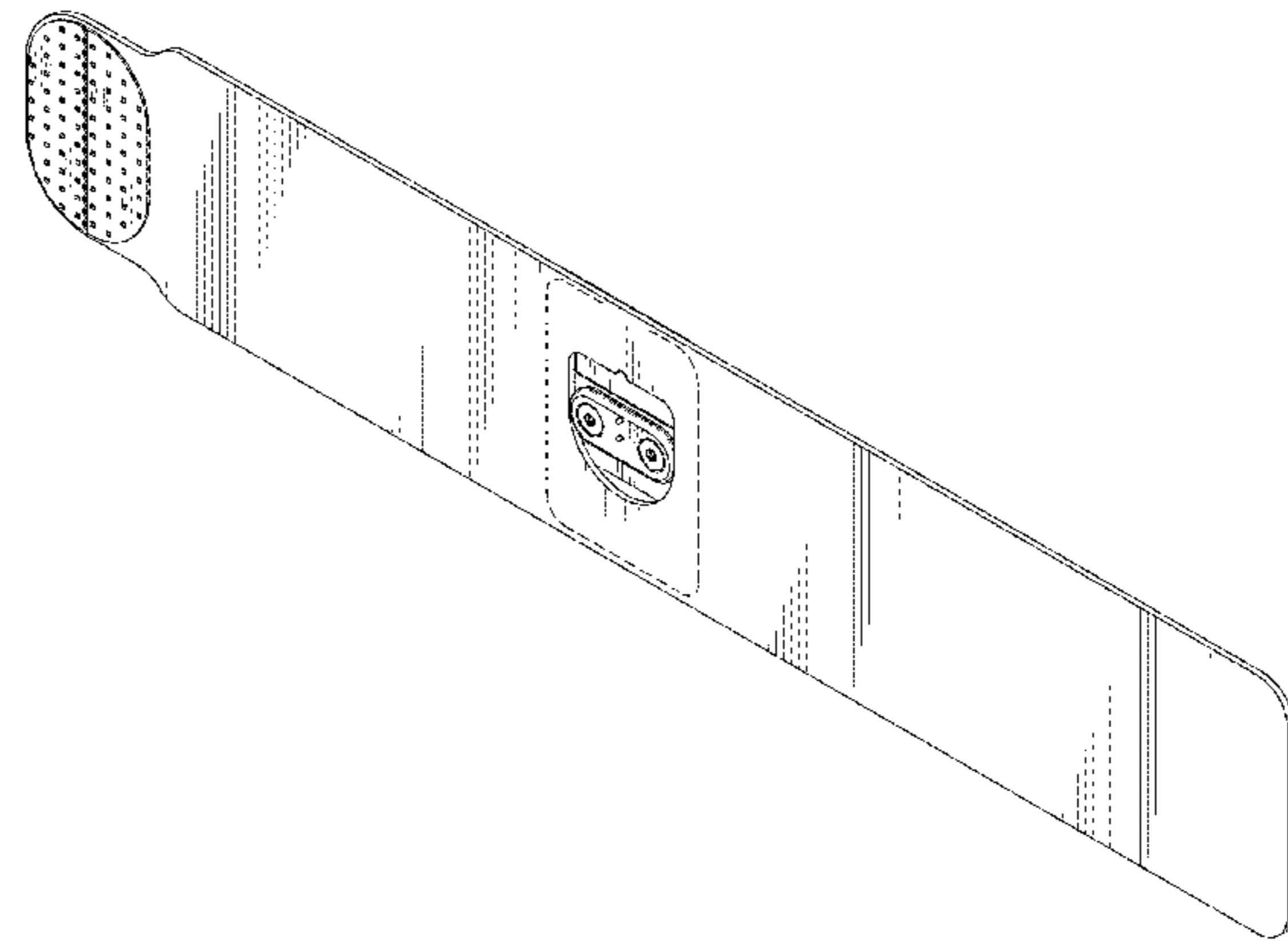
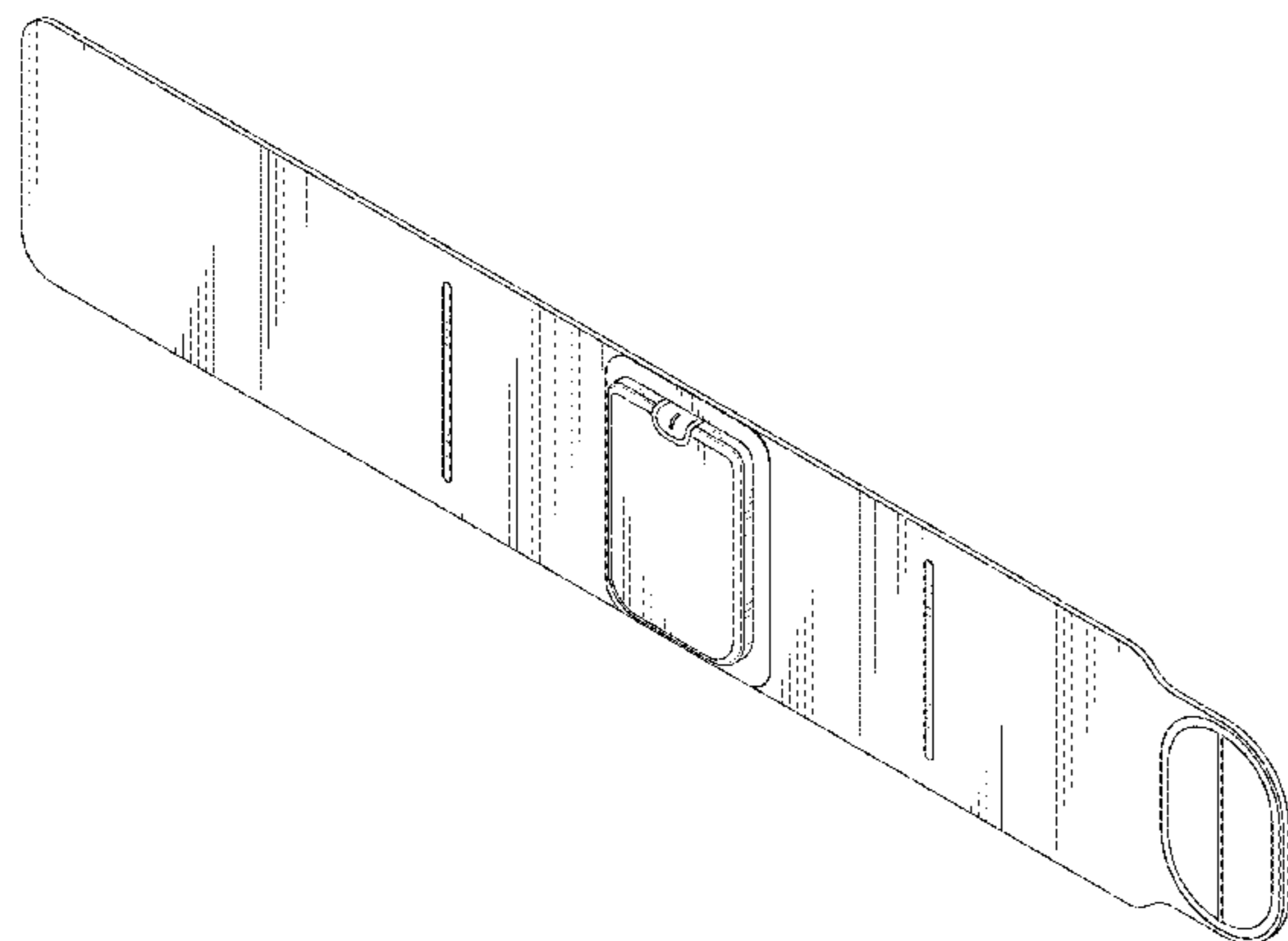
(58) **Field of Classification Search**  
USPC ..... D24/200, 189, 186, 187, 168, 214–215  
CPC ..... A61N 1/04; A61N 1/0456; A61N 1/0404; A61N 1/0452; A61N 1/36021; A61N 1/36042; A61N 1/3606; A61N 1/36057; A61N 1/3605; A61N 1/36014; A61N 1/36; A61N 1/3625; A61N 1/08  
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2,327,874 A	8/1943	Jong
D243,417 S	2/1977	Allen et al.
4,033,356 A	7/1977	Hara
4,121,573 A	10/1978	Crovella et al.
D255,938 S	7/1980	Hawke et al.
4,419,998 A	12/1983	Heath
4,503,863 A	3/1985	Katims
4,605,010 A	8/1986	McEwen
4,630,483 A	12/1986	Engdahl
4,738,250 A	4/1988	Fulkerson et al.
D299,746 S	2/1989	Guldalian, Jr.
5,010,896 A	4/1991	Westbrook
5,063,929 A	11/1991	Bartelt et al.

5,125,100 A	6/1992	Katznelson
5,169,384 A	12/1992	Bosniak et al.
D342,571 S *	12/1993	Givens, Sr. .... D24/186
5,327,902 A	7/1994	Lemmen
5,350,414 A	9/1994	Kolen
5,487,759 A	1/1996	Bastyr et al.
5,562,718 A	10/1996	Palermo
5,755,750 A	5/1998	Petruska et al.
5,797,902 A	8/1998	Netherly
5,806,522 A	9/1998	Katims
5,851,191 A	12/1998	Gozani
D407,822 S	4/1999	Davis et al.
5,948,000 A	9/1999	Larsen et al.
5,991,355 A	11/1999	Dahlke
6,132,386 A	10/2000	Gozani et al.
6,141,587 A	10/2000	Mower
6,146,335 A	11/2000	Gozani
6,161,044 A	12/2000	Silverstone
6,266,558 B1	7/2001	Gozani et al.
6,298,255 B1	10/2001	Cordero et al.
6,312,392 B1	11/2001	Herzon
6,430,450 B1	8/2002	Bach-y-Rita et al.
6,456,884 B1	9/2002	Kenney
D475,138 S	5/2003	Baura et al.
6,662,051 B1	12/2003	Eraker et al.
7,459,984 B2	12/2008	Wang et al.
D598,114 S	8/2009	Cryan
D600,352 S	9/2009	Cryan
D609,353 S	2/2010	Cryan
7,668,598 B2	2/2010	Herregraven et al.
7,720,548 B2	5/2010	King
7,725,193 B1	5/2010	Chu
7,760,428 B2	7/2010	Sieckmann
7,844,325 B2	11/2010	Takehara
7,917,201 B2	3/2011	Gozani et al.
D638,131 S	5/2011	Buckels et al.
8,108,049 B2	1/2012	King
8,121,702 B2	2/2012	King
8,131,374 B2	3/2012	Moore et al.
D669,186 S	10/2012	Gozani
D669,187 S	10/2012	Gozani
8,320,988 B2	11/2012	Axelgaard
8,421,642 B1	4/2013	McIntosh et al.
8,825,175 B2	9/2014	King
8,862,238 B2	10/2014	Rahimi et al.
8,948,876 B2	2/2015	Gozani et al.
9,168,375 B2	10/2015	Rahimi et al.
9,173,581 B2	11/2015	Boettcher et al.
9,220,431 B2	12/2015	Holz hacker
D746,987 S	1/2016	Okuda et al.
D754,355 S	4/2016	Ganapathy et al.
D760,395 S	6/2016	Barbaric et al.
9,452,287 B2	9/2016	Rosenbluth et al.





- Chen CC et al., A comparison of transcutaneous electrical nerve stimulation (TENS) at 3 and 80 pulses per second on cold-pressor pain in healthy human participants, *Clinical Physiology and Functioning Imaging*, 2010, vol. 30(4): 260-268.
- Chen CC et al., An investigation into the effects of frequency-modulated transcutaneous electrical nerve stimulation (TENS) on experimentally-induced pressure pain in healthy human participants, *The Journal of Pain*, 2009, vol. 10(10): 1029-1037.
- Chen CC et al., Differential frequency effects of strong nonpainful transcutaneous electrical nerve stimulation on experimentally induced ischemic pain in healthy human participants, *The Clinical Journal of Pain*, 2011, vol. 27(5): 434-441.
- Chen CC et al., Does the pulse frequency of transcutaneous electrical nerve stimulation (TENS) influence hypoalgesia? A systematic review of studies using experimental pain and healthy human participants, *Physiotherapy*, 2008, vol. 94: 11-20.
- Claydon LS et al., Dose-specific effects of transcutaneous electrical nerve stimulation on experimental pain, *Clinical Journal of Pain*, 2011, vol. 27(7): 635-647.
- Cole, R.J. et al., Automatic Sleep/Wake Identification From Wrist Activity, *Sleep*, 1992, 15(5), p. 461-469.
- Cruccu G. et al., EFNS guidelines on neurostimulation therapy for neuropathic pain, *European Journal of Neurology*, 2007, vol. 14: 952-970.
- Davies Hto et al., Diminishing returns or appropriate treatment strategy?—an analysis of short-term outcomes after pain clinic treatment, *Pain*, 1997, vol. 70: 203-208.
- Desantana JM et al., Effectiveness of transcutaneous electrical nerve stimulation for treatment of hyperalgesia and pain, *Curr Rheumatol Rep*. 2008, vol. 10(6): 492-499.
- Dubinsky RM et al., Assessment: Efficacy of transcutaneous electric nerve stimulation in the treatment of pain in neurologic disorders (an evidence-based review): Report of the therapeutics and technology assessment subcommittee of the american academy of neurology, *Neurology*, 2010, vol. 74: 173-176.
- Fary RE et al., Monophasic electrical stimulation produces high rates of adverse skin reactions in healthy subjects, *Physiotherapy Theory and Practice*, 2011, vol. 27(3): 246-251.
- Fishbain, David A. et al. Does Pain Mediate the Pain Interference with Sleep Problem in Chronic Pain? Findings from Studies for Management of Diabetic Peripheral Neuropathic Pain with Duloxetine, *Journal of Pain Symptom Management*, Dec. 2008;36(6):639-647.
- Fishbain, David A. et al., Transcutaneous Electrical Nerve Stimulation (TENS) Treatment Outcome in Long-Term Users, *The Clinical Journal of Pain*, Sep. 1996;12(3):201-214.
- Food and Drug Administration, Draft Guidance for Industry and Staff: Class II Special Controls Guidance Document: Transcutaneous Electrical Nerve Stimulator for Pain Relief, Apr. 5, 2010.
- Garrison DW et al., Decreased activity of spontaneous and noxiously evoked dorsal horn cells during transcutaneous electrical nerve stimulation (TENS), *Pain*, 1994, vol. 58: 309-315.
- Gilron, I. et al., Chronobiological Characteristics of Neuropathic Pain: Clinical Predictors of Diurnal Pain Rhythmicity, *The Clinical Journal Of Pain*, 2013.
- Hori, T. et al., Skin Potential Activities and Their Regional Differences During Normal Sleep in Humans, *The Japanese Journal of Physiology*, 1970, vol. 20, p. 657-671.
- Jelinek HF et al., Electric pulse frequency and magnitude of perceived sensation during electrocutaneous forearm stimulation, *Arch Phys Med Rehabil*, 2010, vol. 91; 1372-1382.
- Jin DM et al., Effect of transcutaneous electrical nerve stimulation: on symptomatic diabetic peripheral neuropathy: a meta-analysis of randomized controlled trials, *Diabetes Research and Clinical Practice*, 2010, vol. 89: 10-15.
- Johnson MI et al., Analgesic effects of different frequencies of transcutaneous electrical nerve stimulation on cold-induced pain in normal subjects, *Pain*, 1989, vol. 39: 231-236.
- Johnson MI et al., Transcutaneous Electrical Nerve Stimulation (TENS) and TENS-like devices: do they provide pain relief?, *Pain Reviews*, 2001, vol. 8: 7-44.
- Johnson MI et al., Transcutaneous electrical nerve stimulation for the management of painful conditions: focus on neuropathic pain, *Expert Review of Neurotherapeutics*, 2011, vol. 11(5): 735-753.
- Johnson, M.I. et al., An in-depth study of long-term users of transcutaneous electrical nerve stimulation (TENS). Implications for clinical use of TENS. *Pain*. Mar. 1991;44(3):221-229.
- Kaczmarek, Kurt A. et al.. Electrotactile and Vibrotactile Displays for Sensory Substitution Systems. *IEEE Trans. Biomed. Eng.* Jan. 1991;38 (1):1-16.
- Kantor G et al., The effects of selected stimulus waveforms on pulse and phase characteristics at sensory and motor thresholds, *Physical Therapy*, 1994, vol. 74(10): 951-962.
- Keller, Thierry et al., Electrodes for transcutaneous (surface) electrical stimulation. *J. Automatic Control; University of Belgrade*. 2008,18(2):35-45.
- Koumans, A. J. R. et al., Electrodermal Levels and Fluctuations During Normal Sleep, *Psychophysiology*, 1968, 5(3), p. 300-306.
- Kripke, D.F. et al., Wrist Actigraphic Scoring for Sleep Laboratory Patients: Algorithm Development, *Journal of Sleep Research*, 2010, 19(4), p. 612-619.
- Law PPW et al., Optimal stimulation frequency of transcutaneous electrical nerve stimulation on people with knee osteoarthritis, *J Rehabil Med*, 2004, vol. 36: 220-225.
- Leonard G et al., Deciphering the role of endogenous opioids in high-frequency TENS using low and high doses of naloxone, *Pain*, 2010, vol. 151: 215-219.
- Levy et al., A comparison of two methods for measuring thermal thresholds in diabetic neuropathy, *Journal of Neurology, Neurosurgery, and Psychiatry*, 1989, vol. 52: 1072-1077.
- Lykken, D.T., Properties of Electrodes Used in Electrodermal Measurement. *J. Comp. Physiol. Psychol.* Oct. 1959;52:629-634.
- Lykken, D.T., Square-Wave Analysis of Skin Impedance. *Psychophysiology*. Sep. 1970;7(2):262-275.
- Melzack R et al., Pain mechanisms: A New Theory, *Science*, 1965, vol. 150(3699): 971-979.
- Moran F et al., Hypoalgesia in response to transcutaneous electrical nerve stimulation (TENS) depends on stimulation intensity, *The Journal of Pain*, 2011, vol. 12(8): 929-935.
- Oosterhof, Jan et al., Outcome of transcutaneous electrical nerve stimulation in chronic pain: short-term results of a double-blind, randomised, placebo-controlled trial. *J. Headache Pain*. Sep. 2006;7(4):196-205.
- Oosterhof, Jan et al., The long-term outcome of transcutaneous electrical nerve stimulation in the treatment for patients with chronic pain: a randomized, placebo-controlled trial. *Pain Pract*. Sep. 2012;12(7):513-522.
- Pantaleao MA et al., Adjusting pulse amplitude during transcutaneous electrical nerve stimulation (TENS) application produces greater hypoalgesia, *The Journal of Pain*, 2011, vol. 12(5): 581-590.
- Paquet, J. et al., Wake Detection Capacity of Actigraphy During Sleep, *Sleep*, 2007, 30(10), p. 1362-1369.
- Pieber K et al., Electrotherapy for the treatment of painful diabetic peripheral neuropathy: a review, *Journal of Rehabilitation Medicine*, 2010, vol. 42: 289-295.
- Raskin, J. et al., A Double-Blind, Randomized Multicenter Trial Comparing Duloxetine with Placebo in the Management of Diabetic Peripheral Neuropathic Pain, *Pain Medicine*, 2005, 6(5), p. 346-356.
- Sadeh, A., The Role and Validity of Actigraphy in Sleep Medicine: An Update, *Sleep Medicine Reviews*, 2011, vol. 15, p. 259-267.
- Sadosky, A. et al., Burden of Illness Associated with Painful Diabetic Peripheral Neuropathy Among Adults Seeking Treatment in the US: Results from a Retrospective Chart Review and Cross-Sectional Survey, *Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy*, 2013, vol. 6, p. 79-92.
- Scherder, E. J. A. et al., Transcutaneous Electrical Nerve Stimulation (TENS) Improves the Rest-Activity Rhythm in Midstage Alzheimer's Disease, *Behavioral Brain Research*, 1999, vol. 101, p. 105-107.
- Tryon, W. W., Issues of Validity in Actigraphic Sleep Assessment, *Sleep*, 2004, 27(1), p. 158-165.
- Tsai, Y. et al., Impact of Subjective Sleep Quality on Glycemic Control in Type 2 Diabetes Mellitus, *Family Practice*, 2012, vol. 29, p. 30-35.
- Van Bortel, A., Skin resistance during square-wave electrical pulses of 1 to 10 mA. *Med. Biol. Eng. Comput*, Nov. 1977;15(6):679-687.

Van Someren, E. J. W. et al., Gravitational Artefact in Frequency Spectra of Movement Acceleration: Implications for Actigraphy in Young and Elderly Subjects. *Journal of Neuroscience Methods*, 1996, vol. 65, p. 55-62.

Webster, J. B. et al., An Activity-Based Sleep Monitor System for Ambulatory Use, *Sleep*, 1982, 5(4), p. 389-399.

Zelman, D. C. et al., Sleep Impairment in Patients With Painful Diabetic Peripheral Neuropathy, *The Clinical Journal Of Pain*, 2006, 22(8), p. 681-685.

Aurora, R. et al., The Treatment of Restless Legs Syndrome and Periodic Limb Movement Disorder in Adults—An Update for 2012: Practice Parameters with an Evidence-Based Systematic Review and Meta-Analyses, *Sleep*, 2012, vol. 35, No. 8, p. 1039-1062.

Bonnet, M. et al., Recording and Scoring Leg Movements, *Sleep*, 1993, vol. 16, No. 8, p. 748-759.

Boyle, J. et al., Randomized, Placebo-Controlled Comparison of Amitriptyline, Duloxetine, and Pregabalin in Patients With Chronic Diabetic Peripheral Neuropathic Pain, *Diabetes Care*, 2012, vol. 35, p. 2451-2458.

Kovacevic-Ristanovic, R. et al., Nonpharmacologic Treatment of Periodic Leg Movements in Sleep, *Arch. Phys. Med. Rehabil.*, 1991, vol. 72, p. 385-389.

Lopes, L. et al., Restless Legs Syndrome and Quality of Sleep in Type 2 Diabetes, *Diabetes Care*, 2005, vol. 28, No. 11, p. 2633-2636.

Nightingale, S., The neuropathic pain market. *Nature Reviews*, 2012, vol. 11, p. 101-102.

Zucconi, M. et al., The official World Association of Sleep Medicine (WASM) standards for recording and scoring periodic leg movements in sleep (PLMS) and wakefulness (PLMW) developed in collaboration with a task force from the International Restless Legs Syndrome Study Group (IRLSSG), *Sleep Medicine*, 2006, vol. 7, p. 175-183.

Dailey D.L. et al., Transcutaneous Electrical Nerve Stimulation Reduces Pain, Fatigue and Hyperalgesia while Restoring Central Inhibition in Primary Fibromyalgia, *Pain*, Nov. 2013, vol. 154, No. 11, pp. 2554-2562.

\* cited by examiner

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(74) *Attorney, Agent, or Firm* — Pandiscio & Pandiscio

(57) **CLAIM**

The ornamental design for an apparatus for transcutaneous electrical nerve stimulation, as shown and described.

**DESCRIPTION**

FIG. 1 is a front perspective view of a first embodiment the apparatus for transcutaneous electrical nerve stimulation;  
 FIG. 2 is a rear perspective view of the first embodiment of the apparatus for transcutaneous electrical nerve stimulation;  
 FIG. 3 is a front view of the first embodiment of the apparatus for transcutaneous electrical nerve stimulation, taken from the frame of reference of FIG. 1;  
 FIG. 4 is a rear view of the first embodiment of the apparatus for transcutaneous electrical nerve stimulation, taken from the frame of reference of FIG. 1;  
 FIG. 5 is a top view, in elevation, of the top side of the first embodiment of the apparatus for transcutaneous electrical nerve stimulation, taken from the frame of reference of FIG. 1;  
 FIG. 6 is a bottom view, in elevation, of the bottom side of the first embodiment of the apparatus for transcutaneous electrical nerve stimulation, taken from the frame of reference of FIG. 1;

FIG. 7 is a side view, in elevation, of the left side of the first embodiment of the apparatus for transcutaneous electrical nerve stimulation, taken from the frame of reference of FIG. 1;  
 FIG. 8 is a side view, in elevation, of the right side of the first embodiment of the apparatus for transcutaneous electrical nerve stimulation, taken from the frame of reference of FIG. 1;  
 FIG. 9 is a front perspective view of a second embodiment the apparatus for transcutaneous electrical nerve stimulation;  
 FIG. 10 is a rear perspective view of the second embodiment of the apparatus for transcutaneous electrical nerve stimulation;  
 FIG. 11 is a front view of the second embodiment of the apparatus for transcutaneous electrical nerve stimulation, taken from the frame of reference of FIG. 9;  
 FIG. 12 is a rear view of the second embodiment of the apparatus for transcutaneous electrical nerve stimulation, taken from the frame of reference of FIG. 9;  
 FIG. 13 is a top view, in elevation, of the top side of the second embodiment of the apparatus for transcutaneous electrical nerve stimulation, taken from the frame of reference of FIG. 9;  
 FIG. 14 is a bottom view, in elevation, of the bottom side of the second embodiment of the apparatus for transcutaneous electrical nerve stimulation, taken from the frame of reference of FIG. 9;  
 FIG. 15 is a side view, in elevation, of the left side of the second embodiment of the apparatus for transcutaneous electrical nerve stimulation, taken from the frame of reference of FIG. 9;  
 FIG. 16 is a side view, in elevation, of the right side of the second embodiment of the apparatus for transcutaneous electrical nerve stimulation, taken from the frame of reference of FIG. 9;  
 FIG. 17 is a front perspective view of a third embodiment the apparatus for transcutaneous electrical nerve stimulation;  
 FIG. 18 is a rear perspective view of the third embodiment of the apparatus for transcutaneous electrical nerve stimulation;  
 FIG. 19 is a front view of the third embodiment of the apparatus for transcutaneous electrical nerve stimulation, taken from the frame of reference of FIG. 17;  
 FIG. 20 is a rear view of the third embodiment of the apparatus for transcutaneous electrical nerve stimulation, taken from the frame of reference of FIG. 17;  
 FIG. 21 is a top view, in elevation, of the top side of the third embodiment of the apparatus for transcutaneous electrical nerve stimulation, taken from the frame of reference of FIG. 17;  
 FIG. 22 is a bottom view, in elevation, of the bottom side of the third embodiment of the apparatus for transcutaneous electrical nerve stimulation, taken from the frame of reference of FIG. 17;  
 FIG. 23 is a side view, in elevation, of the left side of the third embodiment of the apparatus for transcutaneous electrical nerve stimulation, taken from the frame of reference of FIG. 17; and,  
 FIG. 24 is a side view, in elevation, of the right side of the third embodiment of the apparatus for transcutaneous electrical nerve stimulation, taken from the frame of reference of FIG. 17.

The broken lines are included for the purpose of illustrating unclaimed portions of the apparatus for transcutaneous electrical nerve stimulation and form no part of the claimed design.

**1 Claim, 12 Drawing Sheets**

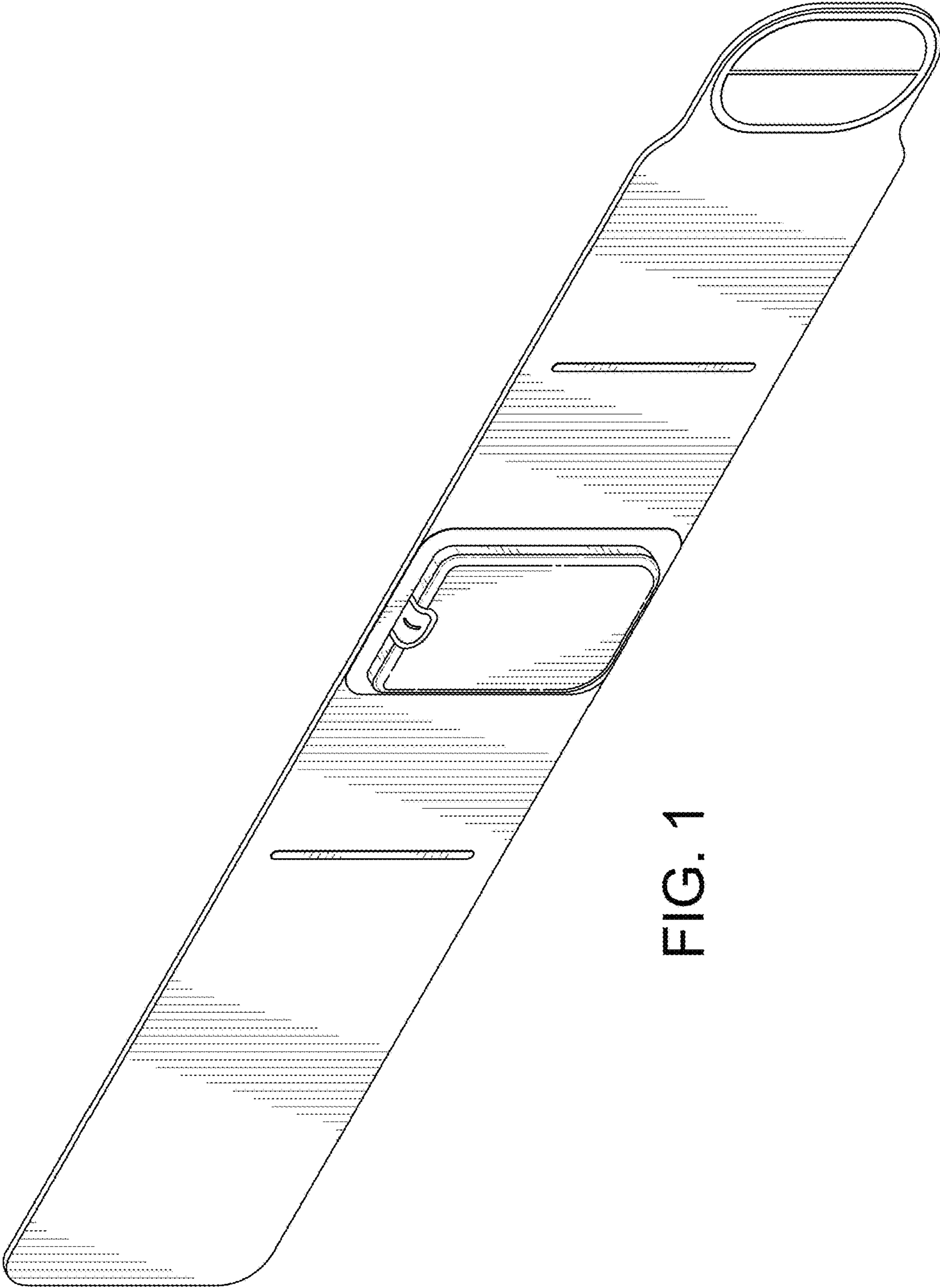


FIG. 1

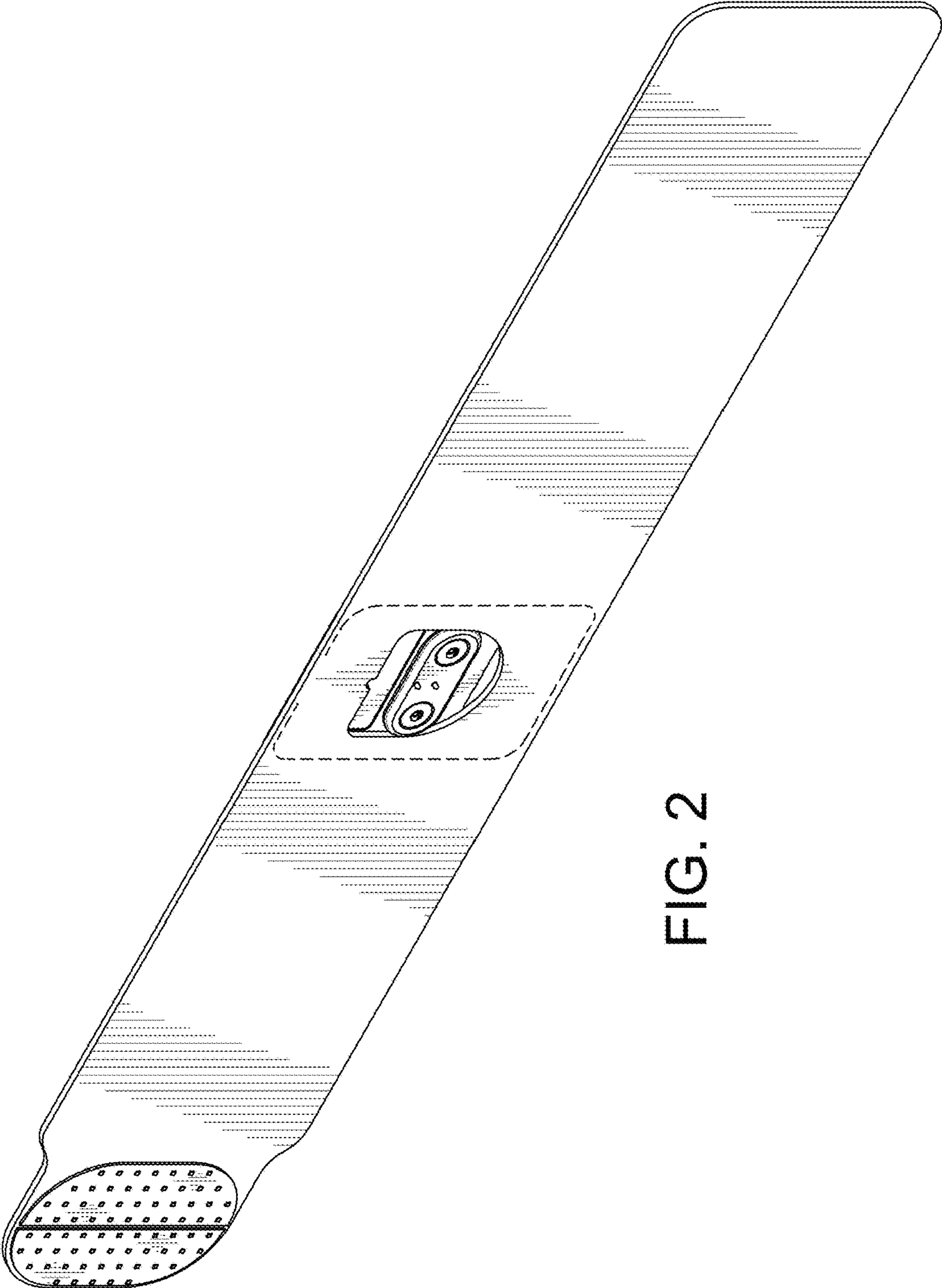


FIG. 2

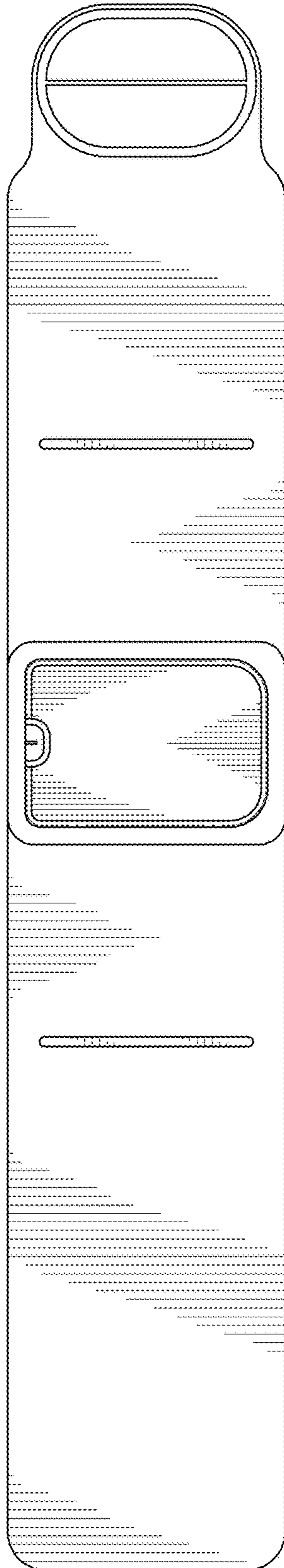


FIG. 3

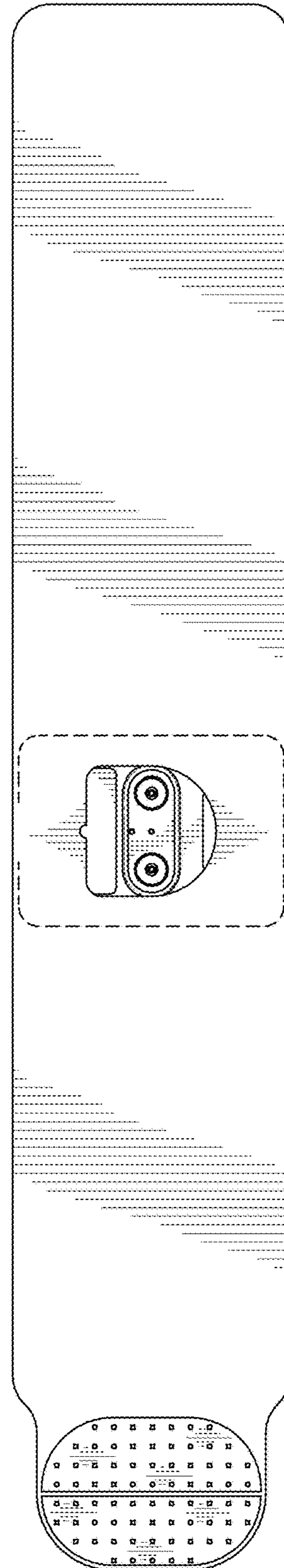


FIG. 4





FIG. 5

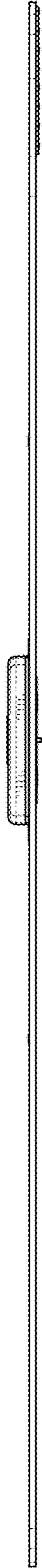


FIG. 6

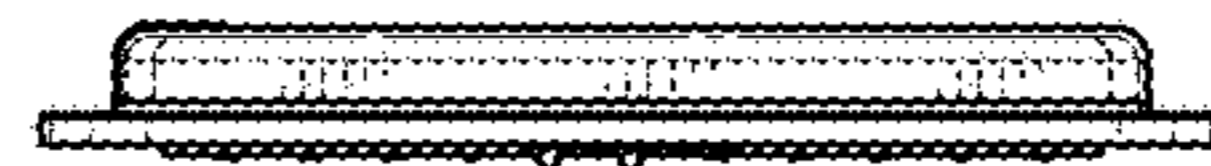


FIG. 7

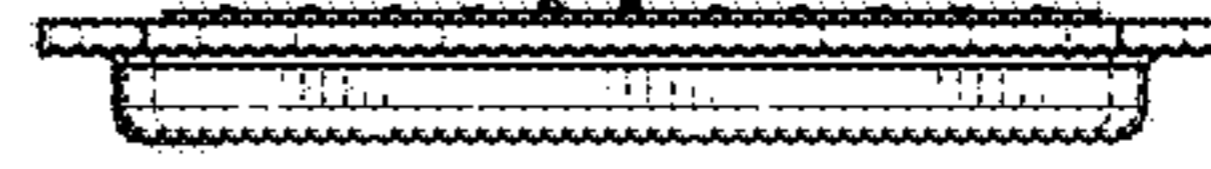


FIG. 8

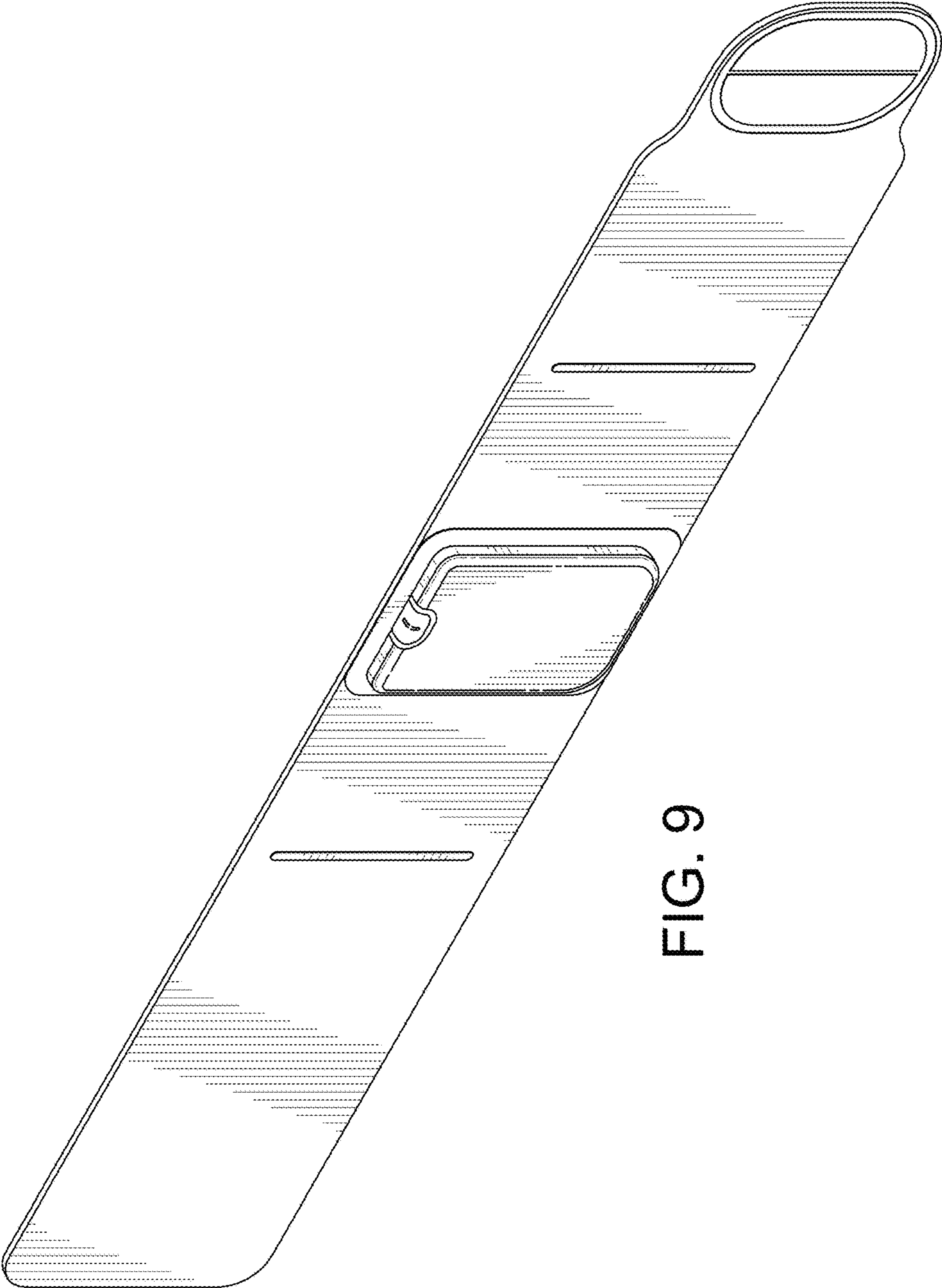


FIG. 9

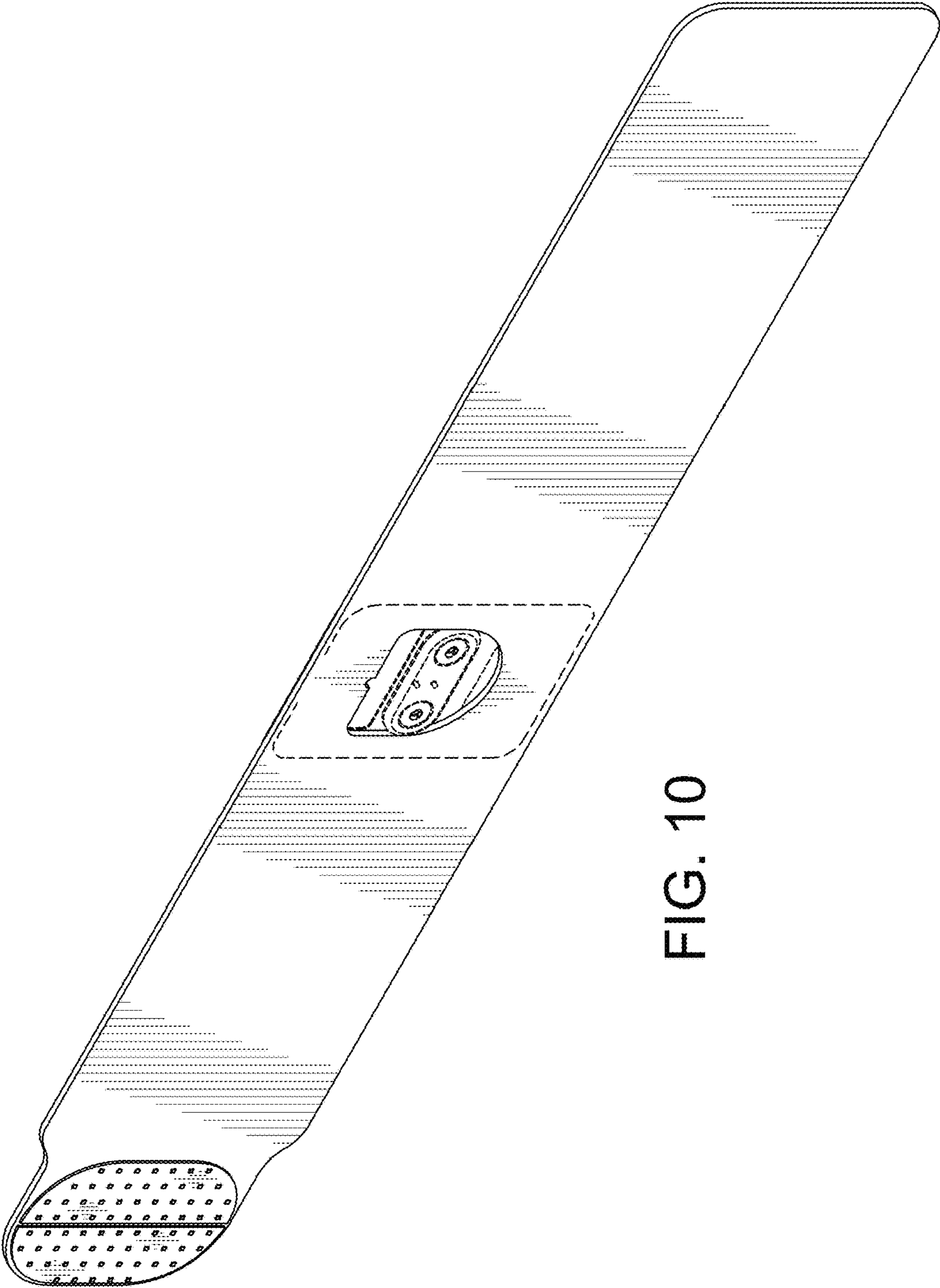


FIG. 10

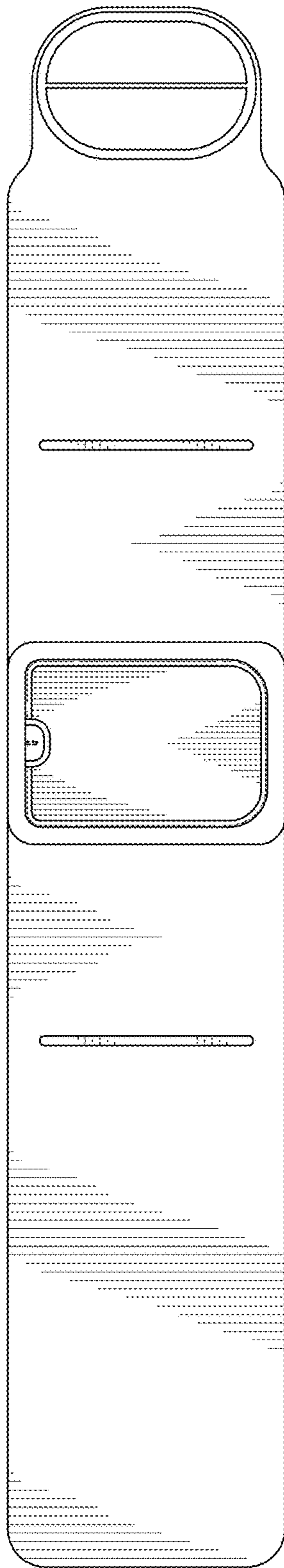


FIG. 11

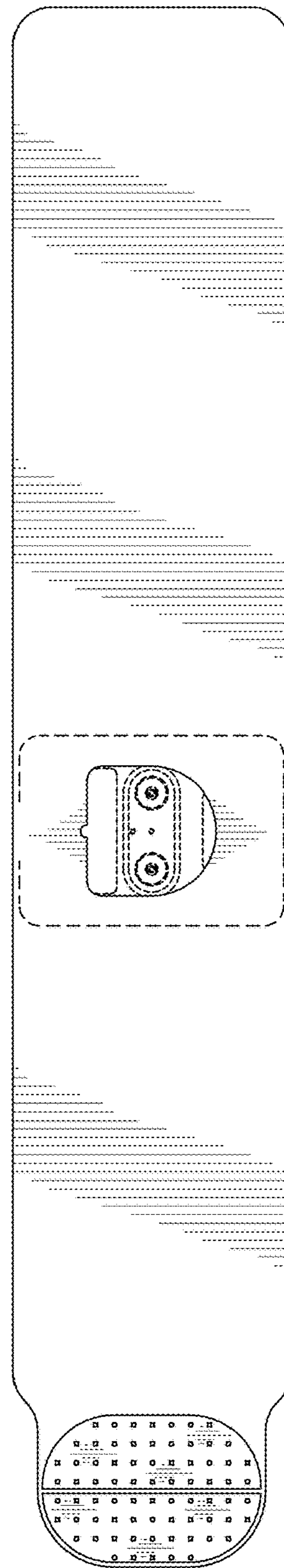


FIG. 12



FIG. 13

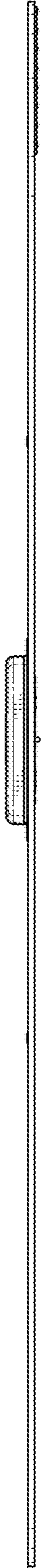


FIG. 14

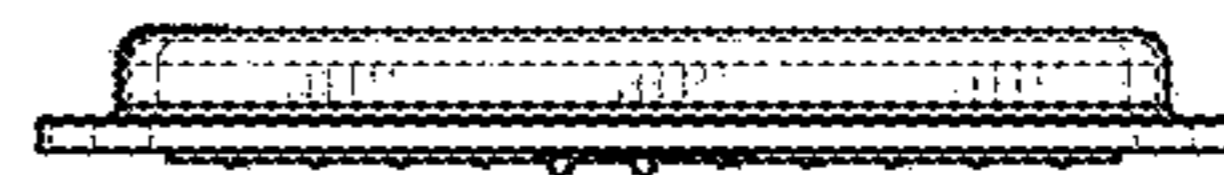


FIG. 15

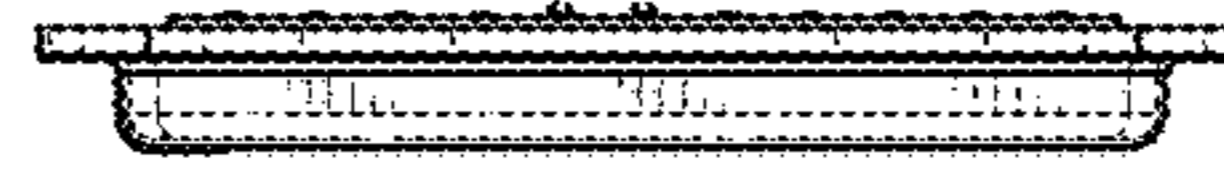


FIG. 16

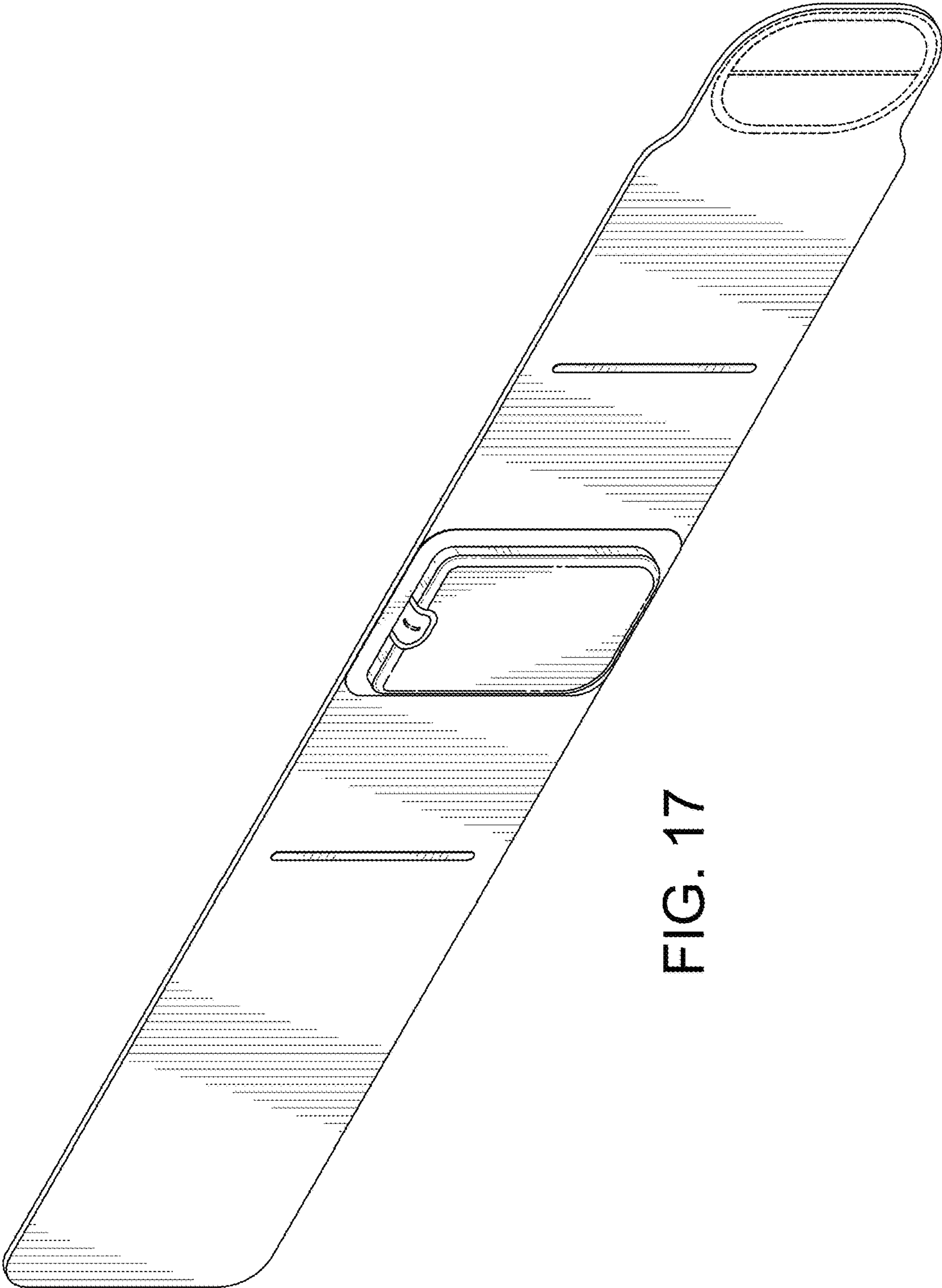


FIG. 17

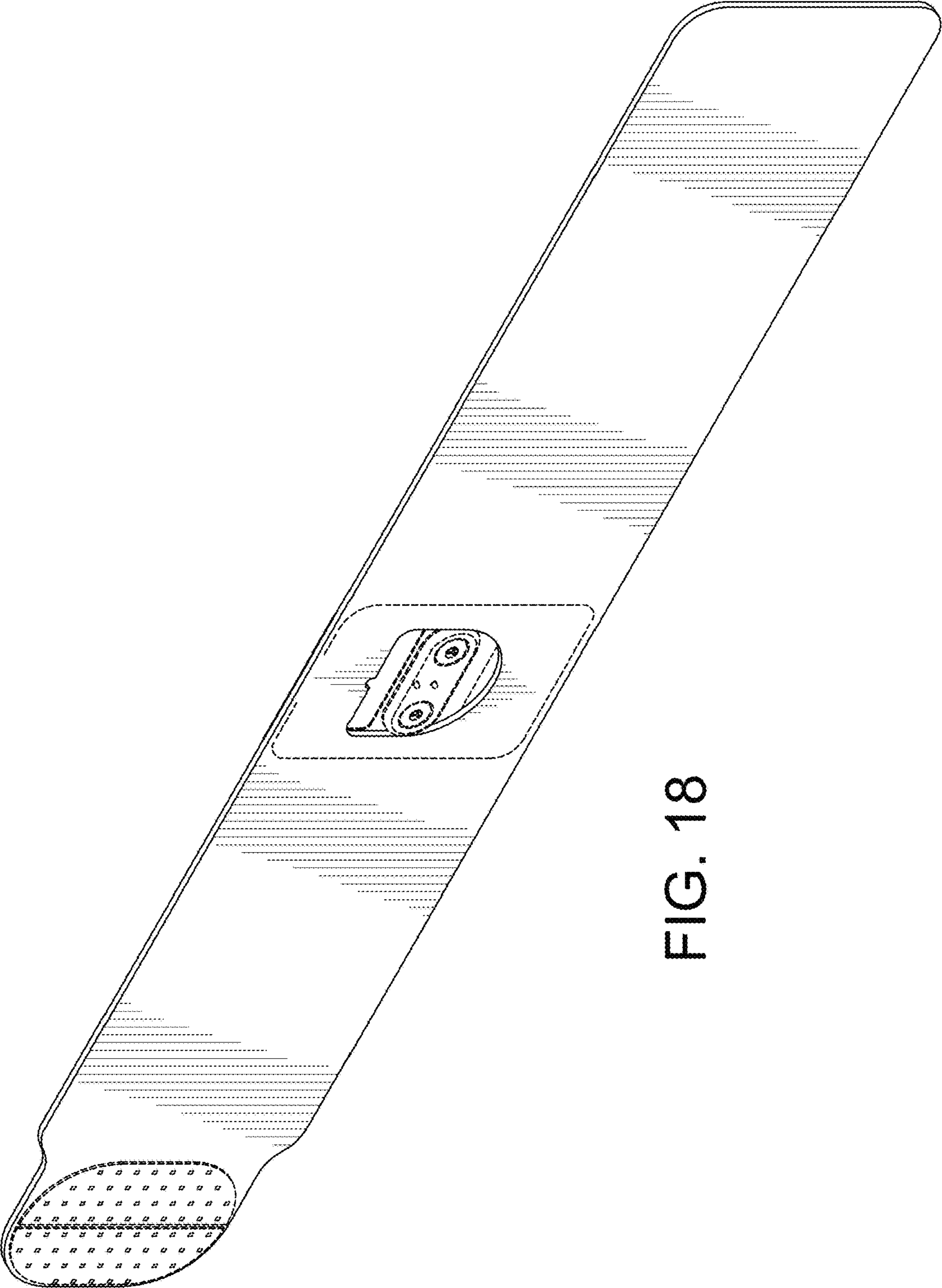


FIG. 18

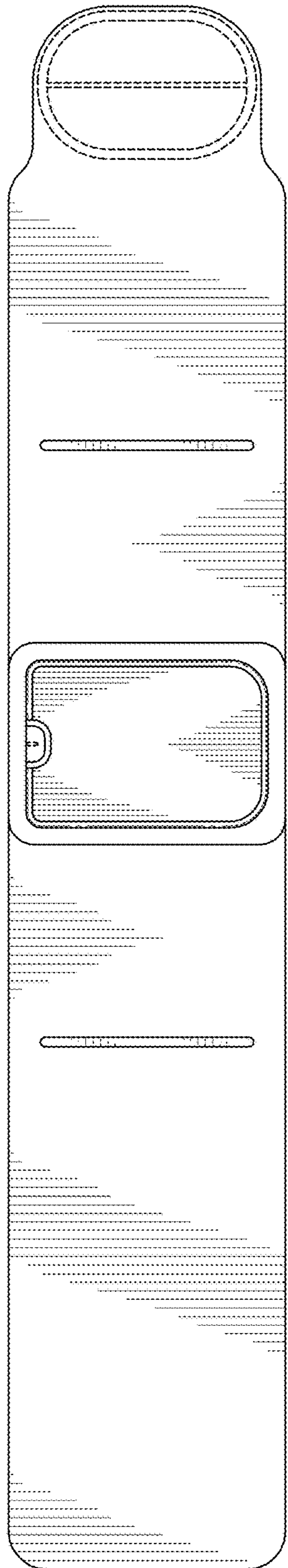


FIG. 19

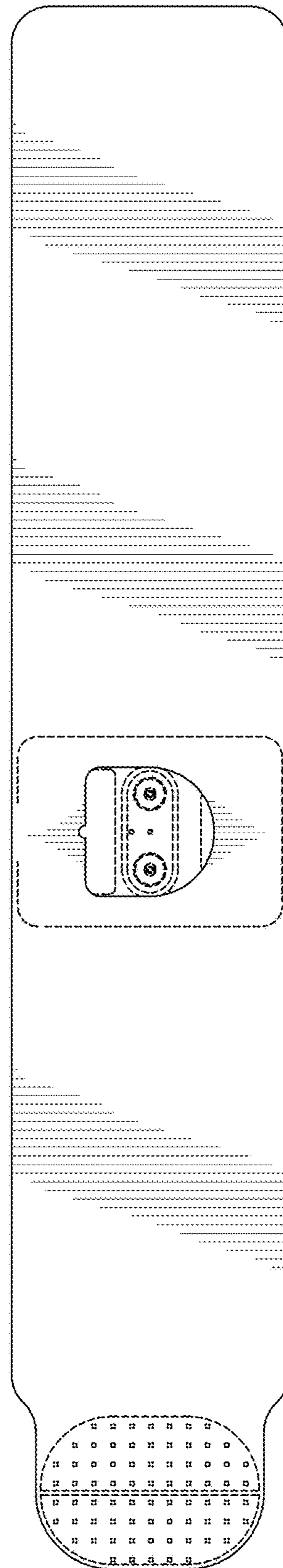


FIG. 20





FIG. 21



FIG. 22

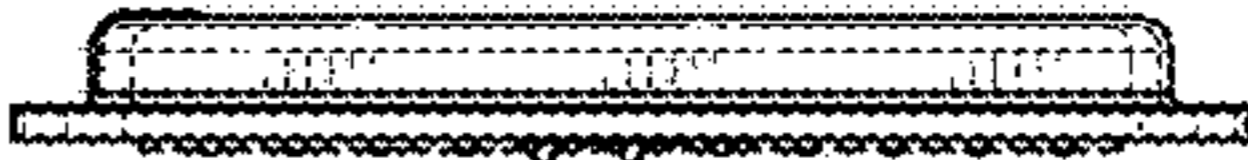


FIG. 23

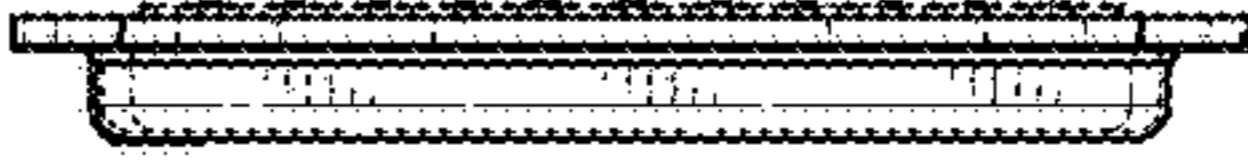


FIG. 24