



US00D480478S

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

(10) **Patent No.:** **US D480,478 S**

(45) **Date of Patent:** **\*\* Oct. 7, 2003**

(54) **PERCUTANEOUS PROBE APPLICATOR**

(75) Inventors: **Paul C. Leonard**, Woodinville, WA  
(US); **Jon M. Bishay**, Woodinville, WA  
(US)

(73) Assignee: **Vertis Neuroscience, Inc.**, Seattle, WA  
(US)

(\*\*) Term: **14 Years**

4,583,449 A	4/1986	Dangel et al.
4,685,466 A	8/1987	Rau
4,686,996 A	8/1987	Ulbrich
4,712,558 A	12/1987	Kidd et al.
D297,047 S	* 8/1988	Hon et al. .... D24/187
4,765,310 A	8/1988	Deagle et al.
4,895,154 A	1/1990	Bartelt et al.
4,934,371 A	6/1990	Malis et al.
4,949,734 A	8/1990	Bernstein
4,953,564 A	9/1990	Berthelsen
4,979,508 A	12/1990	Beck

(21) Appl. No.: **29/130,210**

(List continued on next page.)

(22) Filed: **Sep. 28, 2000**

**FOREIGN PATENT DOCUMENTS**

(51) **LOC (7) Cl.** ..... **24-02**

FR 2 500 309 8/1982

(52) **U.S. Cl.** ..... **D24/147; D24/133; D24/146;**  
D24/187

FR 2500745 9/1982

GB 2 163 355 A 7/1985

(58) **Field of Search** ..... D24/133, 119,  
D24/187, 144, 146, 147; 600/351, 376,  
378, 6; 607/46, 116, 41; 128/897; 606/181,  
182; 604/93

GB 2 255 719 A 5/1991

**OTHER PUBLICATIONS**

(56) **References Cited**

PCT International Search Report for International Application No. PCT/US01/31441; mailed May 7, 2002; Applicant: Vertis Neuroscience, Inc., 8 pages.

(List continued on next page.)

**U.S. PATENT DOCUMENTS**

3,030,959 A	4/1962	Grunert
3,090,151 A	5/1963	Stewart et al.
3,208,452 A	9/1965	Stern
3,938,526 A	2/1976	Anderson et al.
3,943,935 A	3/1976	Cameron
3,983,881 A	10/1976	Wickham
4,139,011 A	2/1979	Benoit et al.
4,153,059 A	5/1979	Fravel et al.
4,207,903 A	6/1980	O'Neill
4,256,116 A	3/1981	Meretsky et al.
4,262,672 A	4/1981	Kief
4,281,659 A	* 8/1981	Farrar et al. .... 600/351
4,284,856 A	8/1981	Hochmair et al.
4,381,012 A	4/1983	Russek
4,408,617 A	10/1983	Auguste
4,431,000 A	2/1984	Butler et al.
4,437,467 A	3/1984	Helfer et al.
4,512,351 A	4/1985	Pohndorf
4,541,432 A	9/1985	Molina-Negro et al.
4,556,064 A	12/1985	Pomeranz et al.

*Primary Examiner*—Ian Simmons

(74) *Attorney, Agent, or Firm*—Perkins Coie LLP

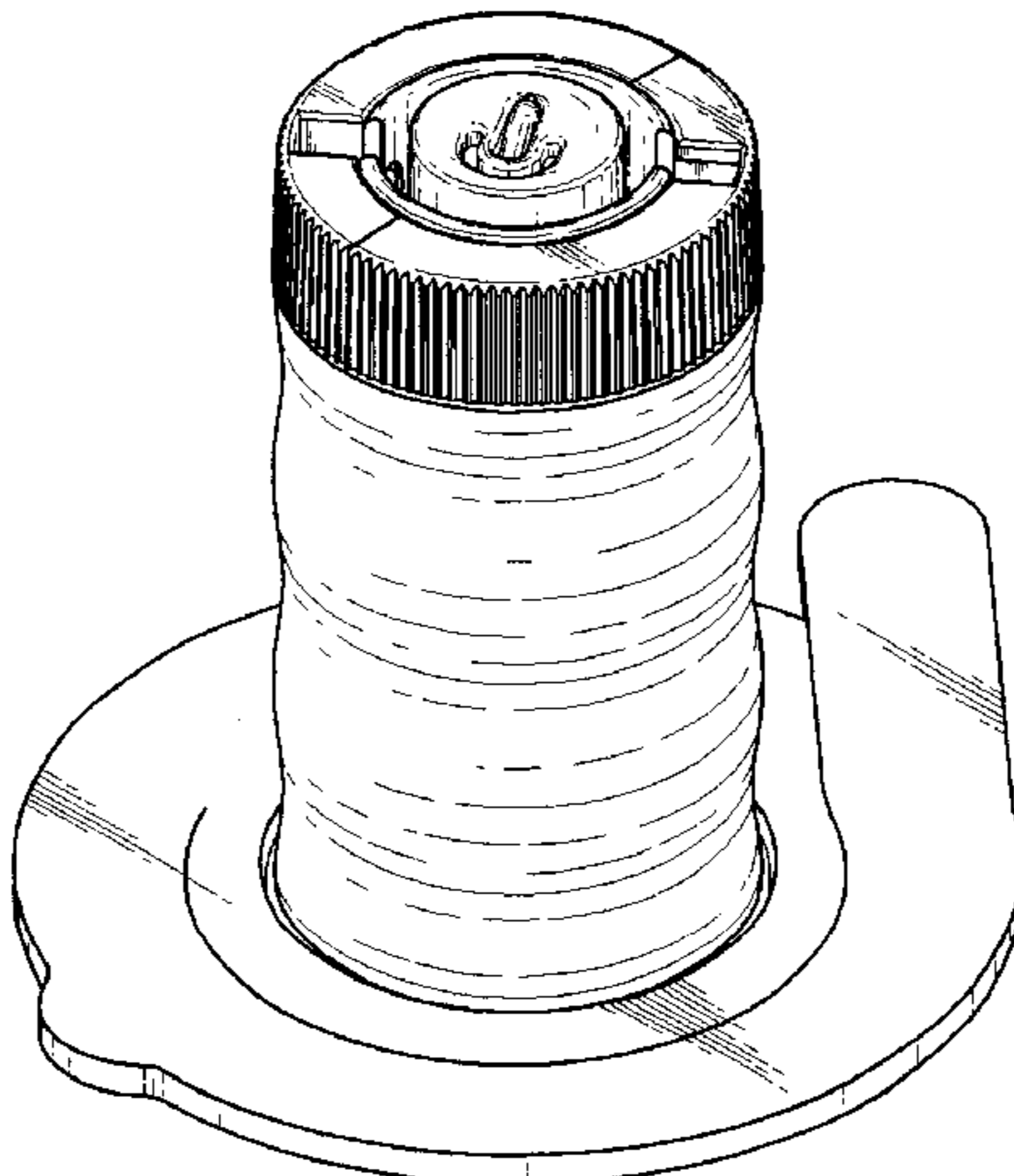
(57) **CLAIM**

The ornamental design for a percutaneous probe applicator, as shown and described.

**DESCRIPTION**

FIG. 1 is a top, left, front isometric view of an embodiment of a percutaneous probe applicator showing our new design. FIG. 2 is a right-side elevational view thereof. FIG. 3 is a left-side elevational view thereof. FIG. 4 is a front elevational view thereof. FIG. 5 is a rear elevational view thereof. FIG. 6 is a top plan view thereof; and, FIG. 7 is a bottom plan view thereof.

**1 Claim, 4 Drawing Sheets**



## U.S. PATENT DOCUMENTS

5,012,811	A	*	5/1991	Malis et al.	128/642
D318,330	S	*	7/1991	Doty et al.	D24/187
5,036,850	A		8/1991	Owens	
5,054,486	A		10/1991	Yamada	
5,094,242	A		3/1992	Gleason et al.	
5,117,826	A		6/1992	Bartelt et al.	
5,211,175	A		5/1993	Gleason et al.	
5,246,014	A		9/1993	Williams et al.	
5,255,691	A		10/1993	Otten	
5,269,304	A		12/1993	Matthews	
5,281,218	A		1/1994	Imran	
5,332,401	A		7/1994	Davey et al.	
D357,069	S	*	4/1995	Plahn et al.	D24/187
5,417,719	A		5/1995	Hull et al.	
5,423,314	A		6/1995	Schmid	
5,439,440	A		8/1995	Hofmann	
5,449,378	A		9/1995	Schouenborg	
5,593,429	A		1/1997	Ruff	
5,649,936	A		7/1997	Real	
5,682,233	A		10/1997	Brinda	
5,702,359	A		12/1997	Hofmann et al.	
5,810,762	A		9/1998	Hofmann	
5,851,223	A		12/1998	Liss et al.	
5,861,015	A		1/1999	Benja-Athon	
5,873,849	A		2/1999	Bernard	
5,928,144	A		7/1999	Real	
5,941,845	A		8/1999	Tu et al.	
5,948,008	A		9/1999	Daikuzono	
5,968,011	A		10/1999	Larsen et al.	
5,968,063	A		10/1999	Chu et al.	
6,009,347	A		12/1999	Hofmann	
6,032,064	A		2/2000	Devlin et al.	
6,035,236	A		3/2000	Jarding et al.	
6,050,992	A		4/2000	Nichols	
6,068,650	A		5/2000	Hofmann et al.	
6,117,077	A		9/2000	Del Mar et al.	
6,122,547	A		9/2000	Benja-Athon	
6,208,893	B1		3/2001	Hofmann	
6,219,569	B1		4/2001	Kelly et al.	
D443,063	S		5/2001	Pisani et al.	
6,269,270	B1		7/2001	Boveja	
6,304,785	B1		10/2001	McCreery et al.	
6,341,237	B1		1/2002	Hurtado	
6,355,021	B1		3/2002	Nielsen et al.	

## OTHER PUBLICATIONS

U.S. patent application Ser. No. 09/667,183, Bishay et al., filed Sep. 21, 2000.

AAMI Neurosurgery Committee; AAMI Implantable Neurostimulator Subcommittee. Implantable peripheral nerve stimulators. Assoc. for the Advancement of Medical Instrumentation (1995) NS15-1995, cover-8, 11 pages.

Ahmed et al., "Percutaneous Electrical Nerve Stimulation (PENS): A Complimentary Therapy for the Management of Pain Secondary to Bony Metastasis", *Clinical Journal of Pain* (Dec. 1998) 14:320-3.

Ahmed et al., "Percutaneous Electrical Nerve Stimulation: An Alternative to Antiviral Drugs for Herpes Zoster," *Anesth. Analg.* (Oct. 1998) 87:911-4.

Almay, B.G.L. et al., "Long-Term High Frequency Transcutaneous Electrical Nerve Stimulation (hi-TNS) in Chronic Pain. Clinical Response and Effects of CSF-Endorphins, Monoamine Metabolites, Substance P-Like Immunoreactivity (SPLI) and Pain Measures", *J. Psychosom. Res.* (1985) 29:247-257, 11 pages.

Baker, L. et al., "Effects of Waveform on Comfort During Neuromuscular Electrical Stimulation", *Clinical Orthopedics and Related Research* (Aug. 1988) 233:75-85.

Ballegaard et al., "Acupuncture and Transcutaneous Electric Nerve Stimulation in the Treatment of Pain Associated with Chronic Pancreatitis", *Scan.J.Rehab.Med.* (Dec. 1985) 20:1249-54.

Balogun et al., "The effects of acupuncture, electroneedling and transcutaneous electric nerve stimulation therapies on peripheral haemodynamic functioning", *Disability and Rehab.* (Feb. 1998) 20:41-8.

Balogun, J., "Effects of Ramp Time on Sensory, Motor and Tolerance Thresholds During Exogenous Electrical Stimulation", *The Journal of Sports Medicine and Physical Fitness* (Dec. 1991) 3:4, 521-526.

BD Safety Products. BD Vacutainer Safety-Lok Blood Collection Set; BD Vacutainer SafetyGlide Blood Collection Assembly and BD Vacutainer Eclipse Blood Collection Needle, 1 page.

BD Safety Flow Lancet—Product Number 366356. BD catalog 1997-2000, Capillary Access, [http://catalog.bd.com/scripts/OBDSheet.exe?FNC=productlist\\_Alistproducts\\_html\\_366356](http://catalog.bd.com/scripts/OBDSheet.exe?FNC=productlist_Alistproducts_html_366356) (Aug. 7, 2001) (3 pages).

BD Vacutainer SafetyGlide Blood Collection Assembly. Quick Reference Card (1999), 1 page.

Brull, S., Silverman, D.G., "Pulse Width, Stimulus Intensity, Electrode Placement, and Polarity During Assessment of Neuromuscular Block", *Anesthesiology* (Oct. 1995) 83:702-709.

Bushnell et al., "Electrical stimulation of peripheral and central pathways for the relief of musculoskeletal pain", *Can.J.Physiol.Pharmacol.* (May 1991) 69:697-703.

Carroll, D., "Randomization is Important in Studies with Pain Outcomes: Systematic Review of Transcutaneous Electrical Nerve Stimulation in Acute Postoperative Pain", *Br J Anaesth.* (1996) 77:798-803.

Cassuto, J. et al., "The Use of Modulated Energy Carried on a High Frequency Wave for the Relief of Intractable Pain", *Int.J.Clin.Pharm.Res.* (1993) XIII(4) 239-241.

Cheng et al., "Electroacupuncture analgesia could be mediated by at least two pain-relieving mechanisms: endorphin and non-endorphin systems", *Life Sciences* (Dec. 3, 1979) 25:1957-62.

Cheng et al., "Electroacupuncture elevates blood cortisol levels in naive horses; sham treatment has no effect", *Intern.J.Neuroscience* (1980) 10:95-7 (1980/no month listed).

Cheng et al., "Electrotherapy of Chronic Musculoskeletal Pain: Comparison of Electroacupuncture and Acupuncture-Like Transcutaneous Electrical Nerve Stimulation", *Clin.J.Pain* (1987) 2:143-9 (1987).

Cramp AF et al., "The Effect of High and Low Frequency Transcutaneous Electrical Nerve Stimulation Upon Cutaneous Blood Flow and Skin Temperature in Healthy Subjects", *Clin.Physio.* (2000) 20:150-7.

Eclipse+ Dual Channel Transcutaneous Electrical Nerve Stimulator User's Manual (1993), 31 pages.

Electrotherapy for Rehabilitation, Empi Cervical Traction, <http://www.empi.com/b/b2.htm>, Oct. 22, 2001, 3 pages.

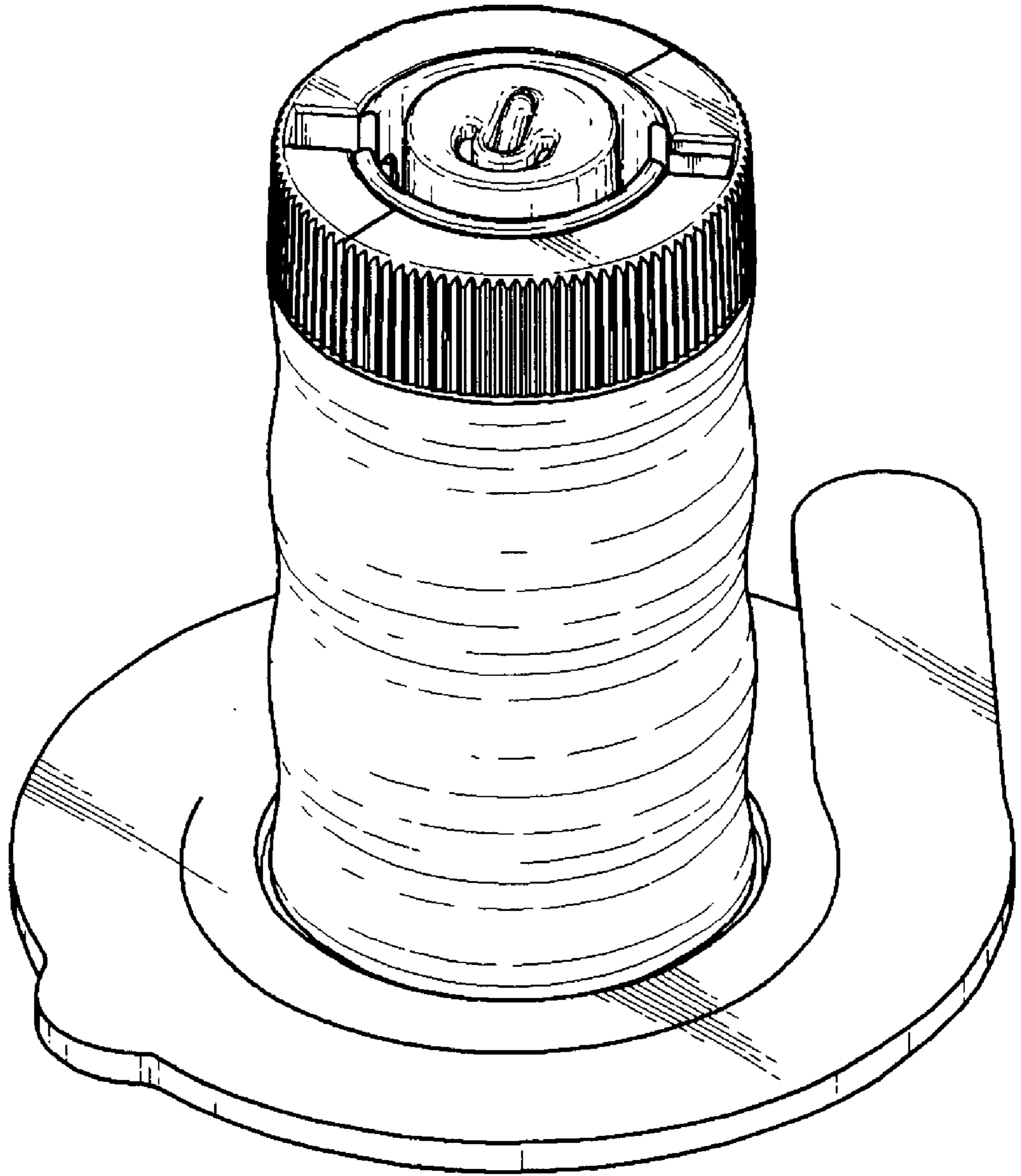
Electrotherapy for Rehabilitation, Empi Cervical Traction, <http://www.empi.com/b/b2.htm>, Mar. 23, 2001, 8 pages.

EPIX XL TENS Instruction Manual, Empi, Inc. (1988), 21 pages.

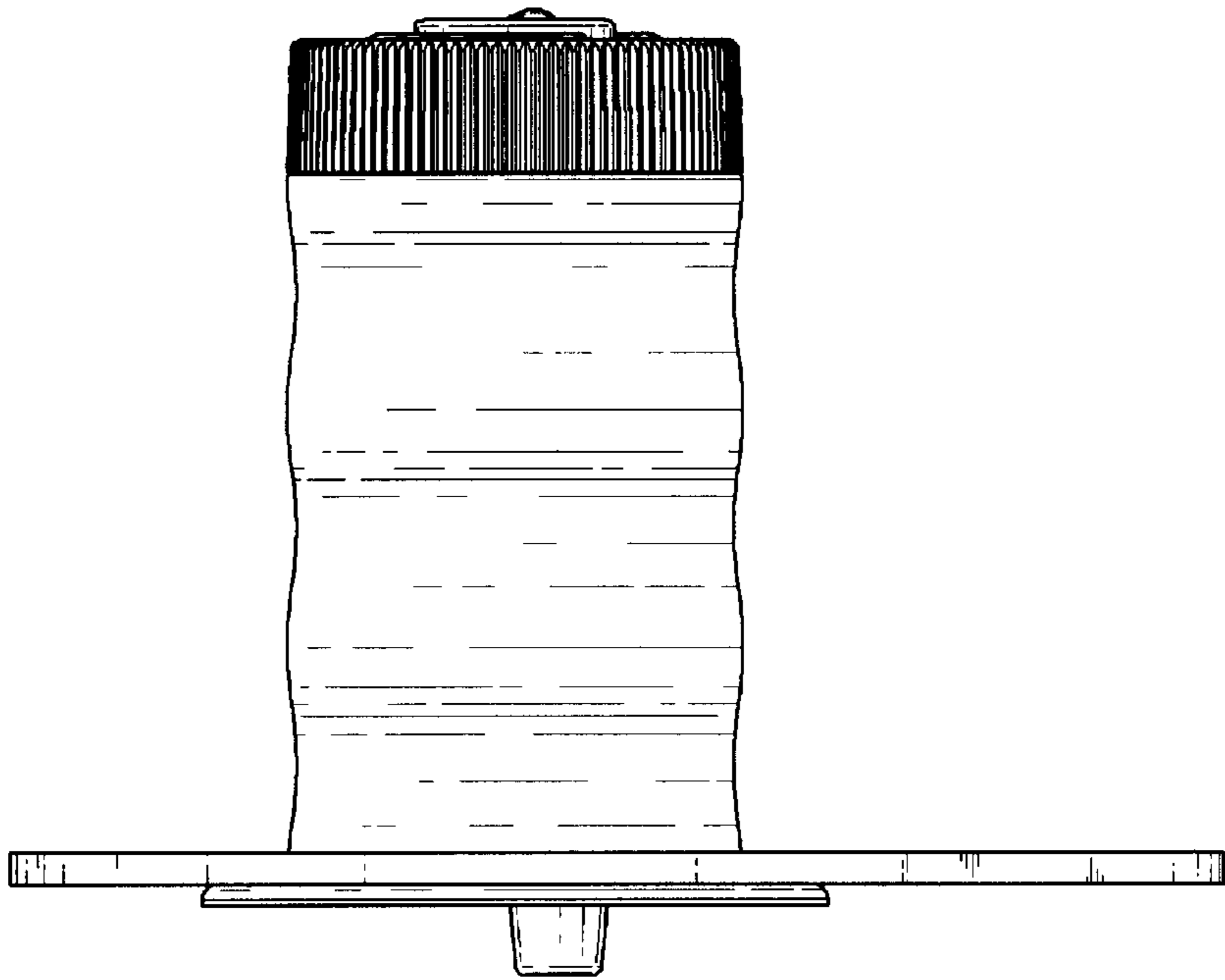
- Foster, N. et al., Manipulation of Transcutaneous Electrical Nerve Stimulation Variables Has No Effect on Two Models of Experimental Pain in Humans, *The Clinical Journal of Pain* (1996) 12:301–310.
- Gadsby et al., “Nerve stimulation for low back pain—a review,” *Nursing Standard* 11:32–3 (Jul. 16, 1997).
- Galletti S.P. et al., Highlights concerning low frequency–high intensity TENS (review). *Minerva Stomatol* (1995) 44:421–9.
- Ghoname et al., “Does the Stimulus Frequency Affect the Analgesic Response to Electrical Stimulation?”, *Anesth. Analg.* (1999) 88:S210, 1 page.
- Ghoname et al., “Percutaneous Electrical Nerve Stimulation for Low Back Pain”, *JAMA* (Mar. 3, 1999) 281:818–23.
- Ghoname et al., “Percutaneous electrical nerve stimulation: an alternative to TENS in the management of sciatica”, *Pain* (Nov. 1999) 83:193–9.
- Ghoname et al., “The Effects of Stimulus Frequency on the Analgesic Response to Percutaneous Electrical Nerve Stimulation in Patients with Chronic Low Back Pain”, *Anesth.Analg.* (Apr. 1999) 88:841–6.
- Ghoname et al., “The Effect of the Duration of Electrical Stimulation on the Analgesic Response”, *Anesth.Analg.* (1999) 88:S211.
- Gopalkrishnann, P., Sluka, K.A., “Effect of Varying Frequency, Intensity, and Pulse Duration of Transcutaneous Electrical Nerve Stimulation on Primary Hyperalgesia in Inflamed Rats”, *Arch.,Phys.Med.Rehabil.* (Jul. 2000) 81:984–990.
- Gracanin, F., Trnkoczy, A. “Optimal Stimulus Parameters for Minimum Pain in the Chronic Stimulation of Innervated Muscle”, *Arch.Phys.Med. Rehabil.* (Jun. 1975) 56:243–249.
- Hamza, M.A. et al., “Effect of the Duration of Electrical Stimulation on the Analgesic Response in Patients with Low Back Pain”, *Anesthesiology* (Dec. 1999), V. 91, No. 6:1622–7.
- Hamza Ma et al., “Effect of the frequency of transcutaneous electrical nerve stimulation on the postoperative opioid analgesic requirement and recovery profile”, *Anesthesiology* (Nov. 1999) 91:1232–8.
- Han Js et al., “Effect of Low and High–Frequency TENS on Met–enkephalin–Arg–Phe and Dynorphin A Immunoreactivity in Human Lumbar CSF”, *Pain* (1991) 47:295–8.
- Healthronics HANS LY257 User Manual, 15 pages.
- Innovative Healthcare: Electrotherapy Pain & Rehabilitation Product Solutions from Rehabilicare. [Includes product description of SporTX and Ortho DX]. 1999, 3 pages, [http://www.mvpdesign.com/sites/rehavilicare/all\\_products.html](http://www.mvpdesign.com/sites/rehavilicare/all_products.html).
- Instruction Manual for the Empi EPIX VT TENS Device, 1997, Dual Channel Transcutaneous Electrical Nerve Stimulator, Empi, Inc., 29 pages.
- Intelect Legend Stim Clinical Reference Manual, vol. 4 Intelect Legend Series, Chattanooga Group, Inc., 31 pages.
- Jette, D., “Effect of Different Forms of Transcutaneous Electrical Nerve Stimulation on Experimental Pain”, *Physical Therapy* (Feb. 1986) 66:2, 187–193.
- Johnson, M.I., “Analgesic Effects of Different Pulse Patterns of Transcutaneous Electrical Nerve Stimulation on Cold–induced Pain in Normal Subjects”, *Journal of Psychosomatic Research* (1991) 35:2–3; 313–321.
- Johnson, MI, “Analgesic Effects of Different Frequencies of Transcutaneous Electrical Nerve Stimulation on Cold–Induced Pain in Normal Subjects”, *Pain* (1989) 39:231–6.
- Johnson, MI, et al. “An In–Depth Study of Long Term Users of Transcutaneous Electrical Nerve Stimulation (TENS). Implications for Clinical Use of TENS”, *Pain* (1991) 44:221–9.
- Katims, J.J. et al., “Transcutaneous Nerve Stimulation. Frequency and Waveform Specificity in Humans”, *Appl. Neurophysiol* (1986) 49:86–91.
- Landau et al., “Neuromodulation Techniques for Medically Refractory Chronic Pain”, *Annu.Rev.Med.* 44:279–87 (1993)/no month listed (annual publication).
- Leem, J., “Electrophysiological evidence for the antinociceptive effect of transcutaneous electrical stimulation on mechanically evoked responsiveness of dorsal horn neurons in neuropathic rats”, *Neuroscience Letters* (1995) 192:197–200.
- Lehmann et al., “Efficacy of Electroacupuncture and TENS in the Rehabilitation of Chronic Low Back Pain Patients”, *Pain* (Sep. 1986) 26:277–90.
- Liss S., Liss B., “Physiological and Therapeutic Effects of High Frequency Electrical Pulses”, *Integr.Physio.Behav. Sci.* (Apr.–Jun. 1996) 31:88–94.
- Model AWQ–104B Multi–Purpose Electronic Acupuncture Instruction Manual, 10 pages.
- Marchand, S., et al., “Modulation of Heat Pain Perception by High Frequency Transcutaneous Electrical Nerve Stimulation (TENS)”, *Clin.J.Pain* (1991) 7:122–9.
- Moreno–Aranda J., “Electrical Parameters for over–the–skin muscle stimulation”, *J. Biomechanics* (1981) 14:9, 579–585.
- Moreno–Aranda J., Seireg, A., “Investigation of over–the–skin electrical stimulation parameters for different normal muscles and subjects”. *J. Biomechanics* (1981) 14:9; 587–593.
- O’Brien, WJ, “Effect of Transcutaneous Electrical Nerve Stimulation on Human Blood B–Endorphin Levels”, *Physical Therapy* (Sep. 1984) 64:1367–1374.
- Omura, Y., “Basic electrical parameters for safe and effective electro–therapeutics [electroacupuncture, TES, TENMS (or TEMS), TENS and electro–magnetic field stimulation with or without drug field] for pain, neuromuscular skeletal problems, and circulatory disturbances”, *Acupuncture & Electro–Therapeutics Res.* (1987) 12:201–25.
- Omura, Y., “Electrical parameters for safe and effective electro–acupuncture and transcutaneous electrical stimulation: Threshold potentials for tingling muscle contraction and pain; and how to prevent adverse effects of electro–therapy”, *Acupuncture & Electro–Therapeutics Res.* 10:335–7 (1985).
- Ordog, G., “Transcutaneous Electrical Nerve Stimulation Versus Oral Analgesic: A Randomized Double–Blind Controlled Study in Acute Traumatic Pain”, *American Journal of Emergency Medicine* (Jan. 1987) 5:1, 6–10.
- Ortho DX Product Data Sheet.
- Pointer F–3 Instruction Manual, ITO Co., Ltd., 10 pages.
- Romita et al., “Parametric Studies on Electroacupuncture–Like Stimulation in a Rat Model: Effects of Intensity, Frequency, and Duration of Stimulation on Evoked Antinociception”, *Brian Res.Bull.* (1997) 42:289–96.
- Rooney, J.G., et al., “Effect of Variation in the Burst and Carrier Frequency Modes of Neuromuscular Electrical Stimulation on Pain Perception of Healthy Subjects”, *Phys.–Ther.* (Nov. 1992) 72:11, 800–808.

- Sluka, K.A., "Treatment with Either High or Low Frequency TENS Reduces the Secondary Hyperalgesia Observed After Injection of Kaolin and Carrageenan into the Knee Joint", *Pain* (1998) 77:97-102.
- SMP-plus. The Pain Relief Solution for Hard to Treat Patients, Rehabilcare (2 pages).
- Somers, D.L., "High-Frequency Transcutaneous Electrical Nerve Stimulation Alters Thermal but not Mechanical Allodynia Following Chronic Construction Injury of the Rat Sciatic Nerve", *Arch.Phys.Med.Rehabil.* (Nov. 1998) 79:1370-6.
- Sportx Product Data Sheet.
- Starobinets, M., Volkova, L., [Analgesic Effect of High-Frequency and Acupuncture-Like Transcutaneous Electric Stimulation of Nerve Fibers in Spinal Osteochondritis]. *Zh Nevropatol Psikhiatr Im S. S. Korsakova* (1985) 85-350-4.
- Ulett et al., "Electroacupuncture: Mechanisms and Clinical Application," *Biol. Psych.* 44:129-38 (Jul. 15, 1998).
- Van Doren, CL, "Contours of Equal Perceived Amplitude and Equal Perceived Frequency for Electrocutaneous Stimuli", *Percept.Psychophys.* (1997) 59:613-22.
- White, P.F. et al., "Percutaneous Neuromodulation Therapy: Does the Location of Electrical Stimulation Effect the Acute Analgesic Response?", *Anesth. Analg.* (2000) 91:1-6.
- White, P.F. et al., "The Effect of Montage on the Analgesic Response to Percutaneous Neuromodulation Therapy", *Anesth. Analg.* (2001) 92:483-7.
- U.S. patent application Ser. No. 09/452,663, entitled "Percutaneous Electrical Therapy System Providing Electrode Axial Support," filed on Dec. 1, 1999.
- U.S. patent application Ser. No. 09/452,508, entitled "Percutaneous Electrical Therapy System with Electrode Depth Control," filed on Dec. 1, 1999.
- U.S. patent application Ser. No. 09/451,795 entitled "Percutaneous Electrical Therapy System with Position Maintenance," filed on Dec. 1, 1999.
- U.S. patent application Ser. No. 09/451,799 entitled "Electrode Introducer for a Percutaneous Electrical Therapy System," filed on Dec. 1, 1999.
- U.S. patent application Ser. No. 09/452,510, entitled "Percutaneous Electrical Therapy System for Minimizing Electrode Insertion Discomfort," filed on Dec. 1, 1999.
- U.S. patent application Ser. No. 09/451,800, entitled "Electrode Assembly for a Percutaneous Electrical Therapy System," filed on Dec. 1, 1999.
- U.S. patent application Ser. No. 09/451,796, entitled "Electrode Remover for a Percutaneous Electrical Therapy System," filed on Dec. 1, 1999.
- U.S. patent application Ser. No. 09/451,547, entitled "Percutaneous Electrical Therapy System with Sharp Point Protection," filed on Dec. 1, 1999.
- U.S. patent application Ser. No. 09/452,477, entitled "Percutaneous Electrical Therapy System with Electrode Entry Angle Control," filed on Dec. 1, 1999.
- U.S. patent application Ser. No. 09/666,931, entitled "Method And Apparatus for Repositioning a Percutaneous Probe," filed on Sep. 21, 2000.

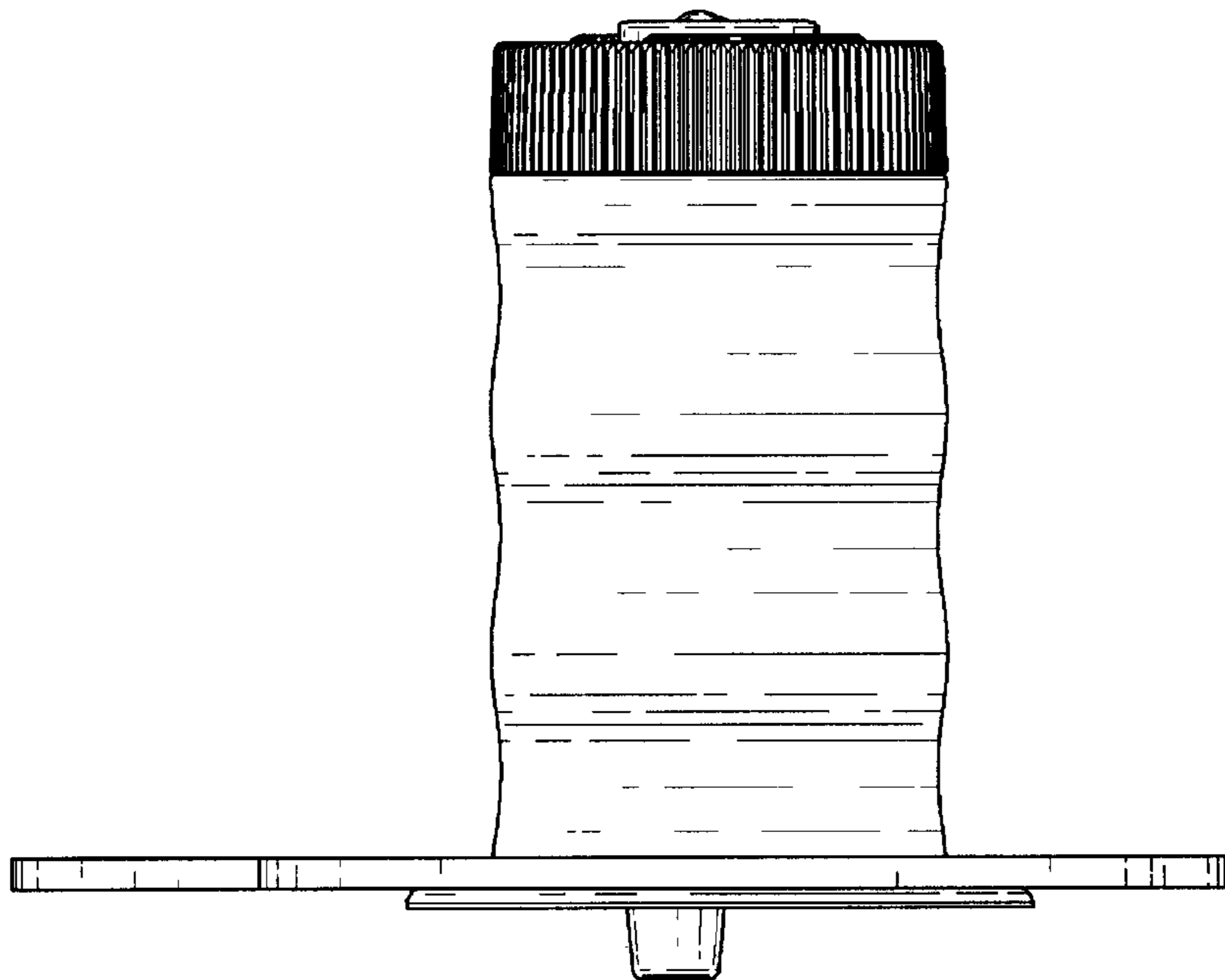
\* cited by examiner



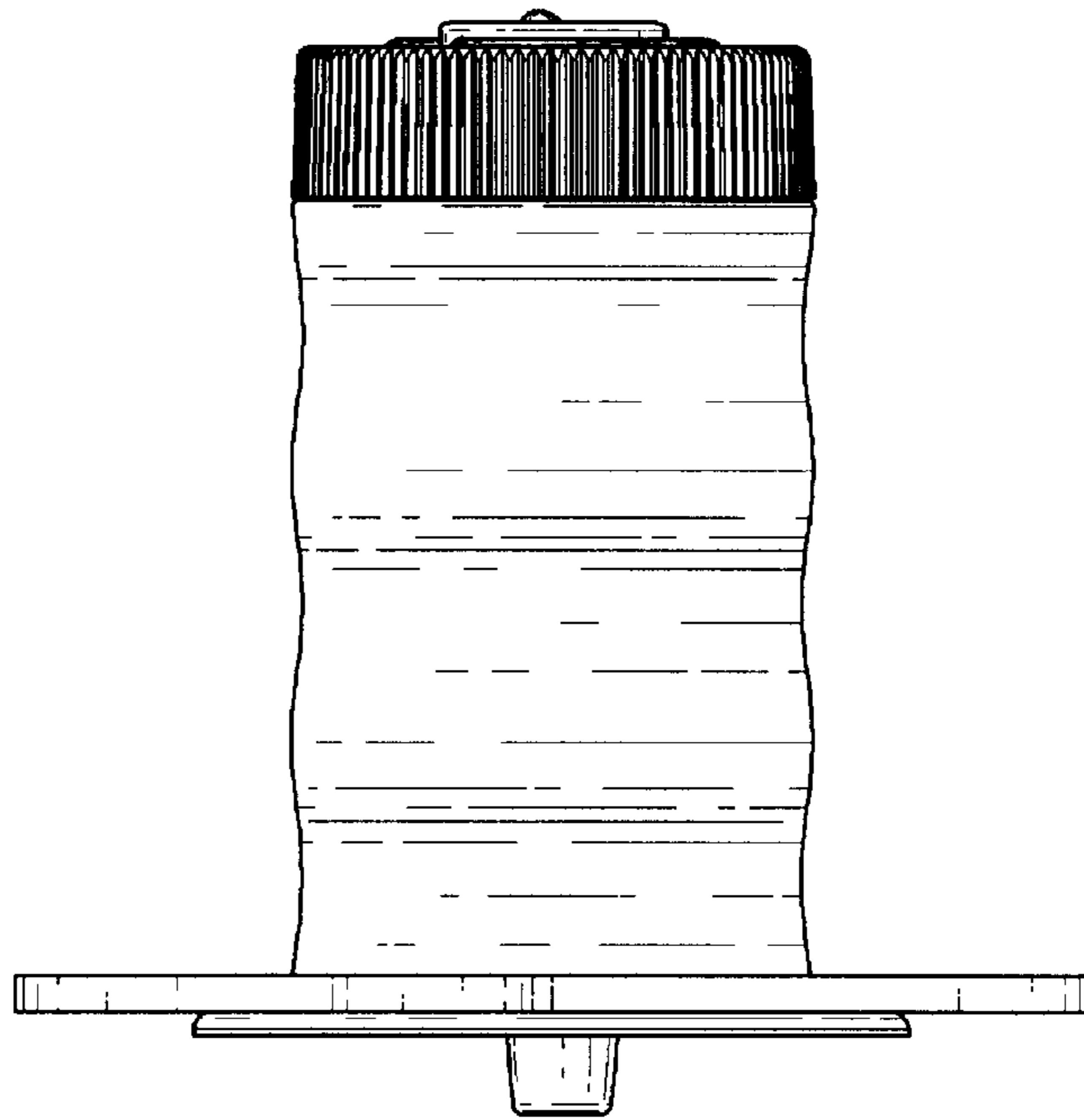
*Fig. 1*



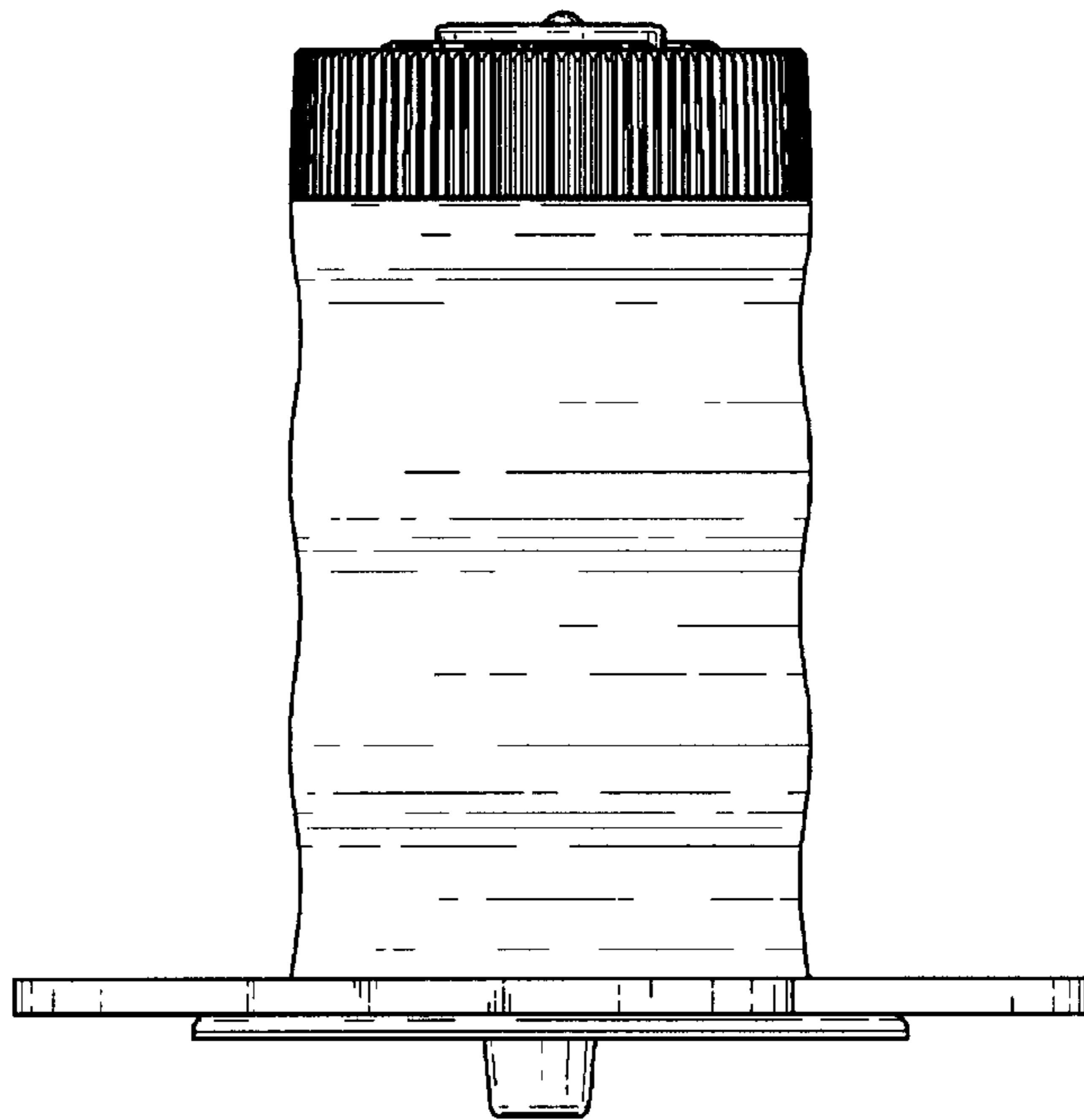
*Fig. 2*



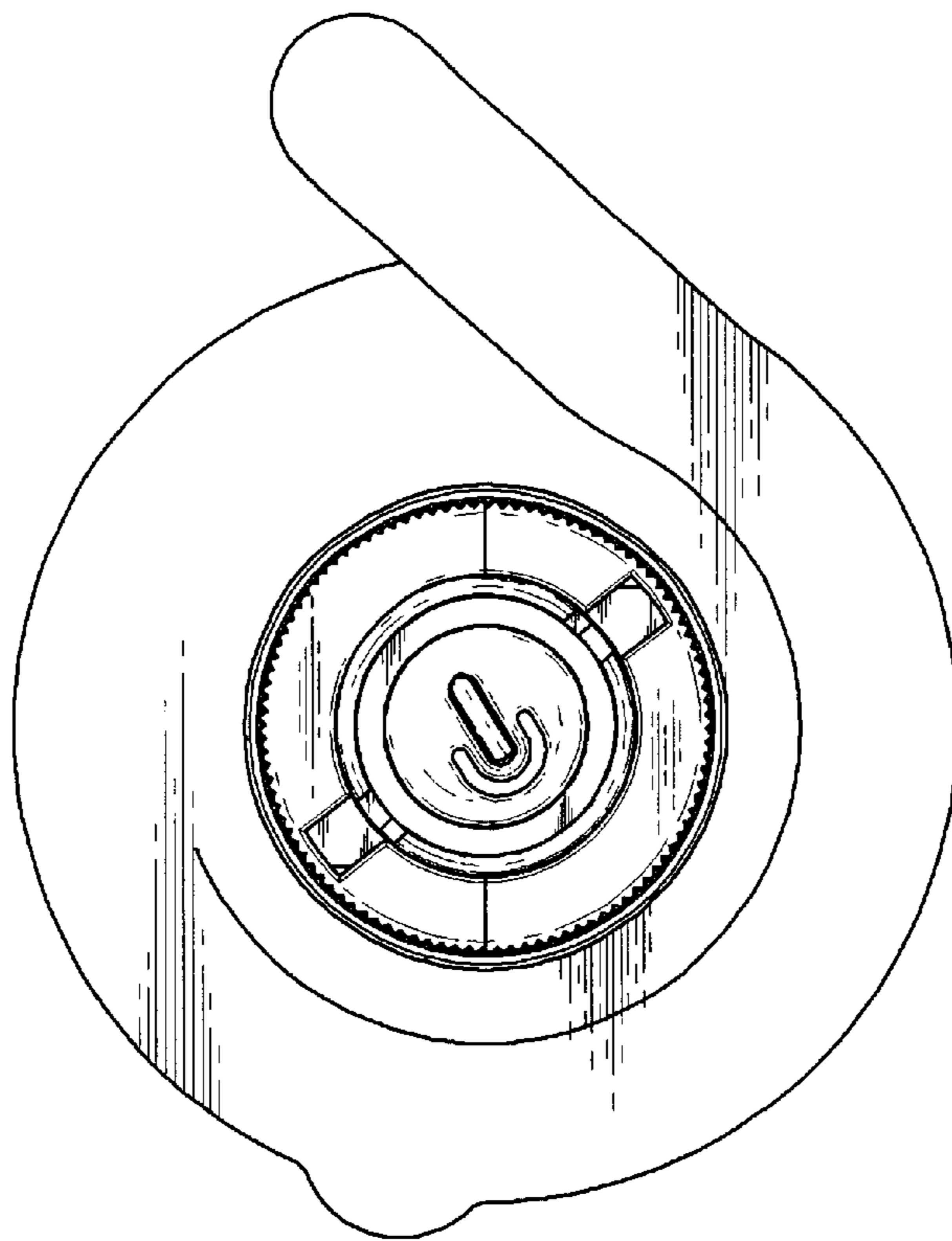
*Fig. 3*



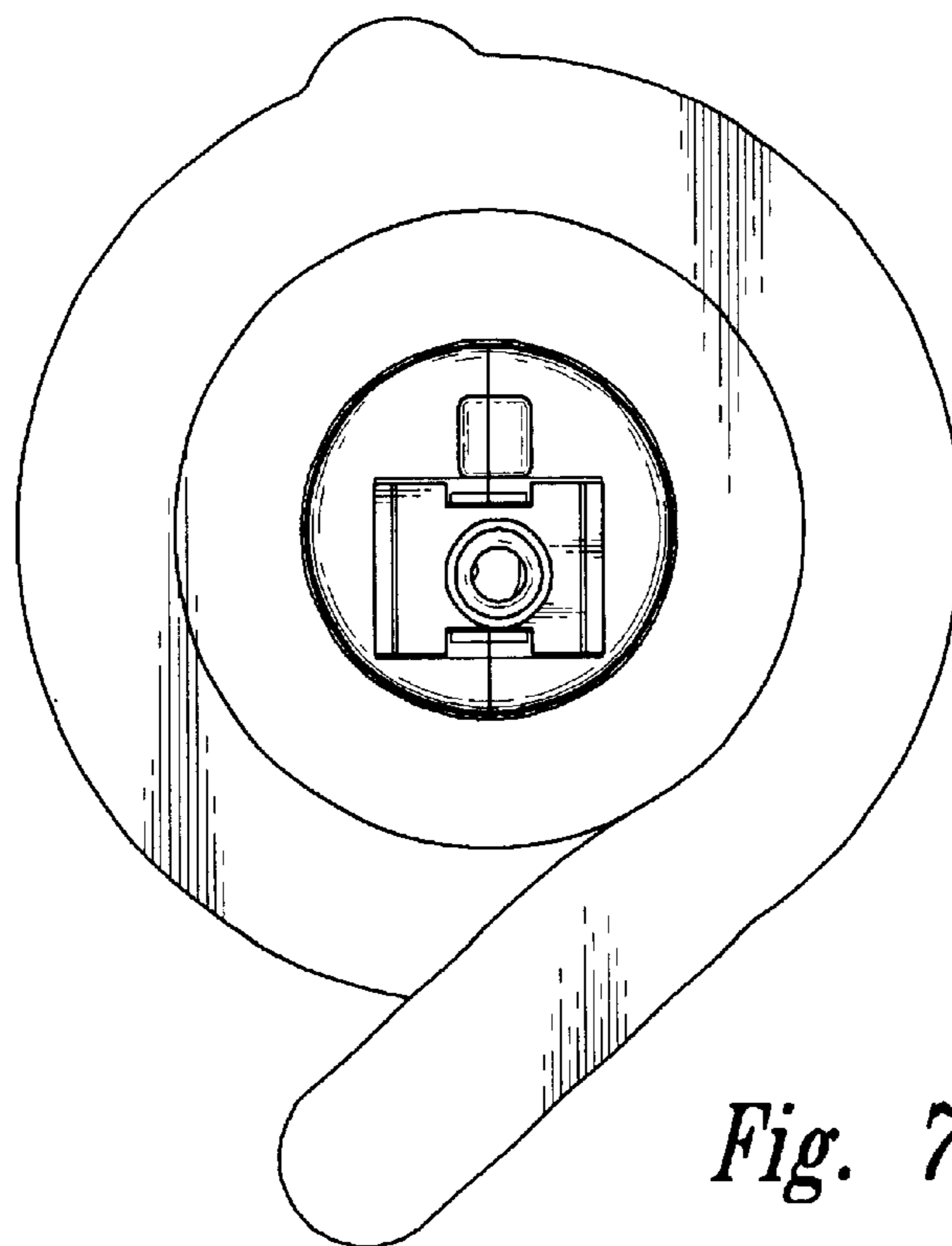
*Fig. 4*



*Fig. 5*



*Fig. 6*



*Fig. 7*