United States Patent

Ness

[15] 3,656,481

[45] Apr. 18, 1972

[54] MAGNETIC OPHTHALMIC INSTRUMENT FOR EYE THERAPY

[72] Inventor: **Richard A. Ness**, 714 South Mills, Fergus Falls, Minn. 56537

[22] Filed: **Aug. 1, 1969**

[21] Appl. No.: **846,709**

[52] **U.S. Cl.** **128/260**, 128/1.4

[51] **Int. Cl.** **A61m 31/00**

[58] **Field of Search** 128/1.3, 1.4, 260, 354, 303, 128/304, 305, 1.5; 294/65.5

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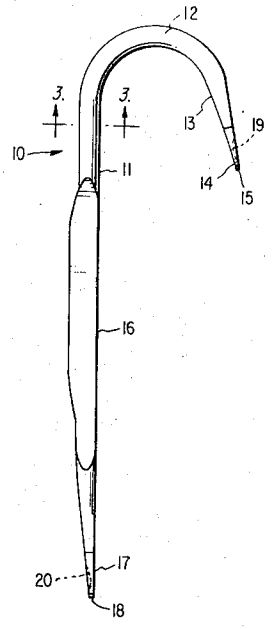
Primary Examiner—Robert W. Michell

Attorney—Steven D. Goldby

[57] **ABSTRACT**

An ophthalmic instrument for manipulating magnetically attractable objects against the eyeball comprising a shank terminating at least at one end in a terminal portion which is flat and magnetic, said terminal portion having a blunt tip, whereby said instrument can be used to insert or remove magnetically attractable objects against the eyeball by attraction of said objects to said flat and magnetic terminal portion(s) of said instrument. One terminal portion of a preferred instrument comprises a curved arm member.

26 Claims, 8 Drawing Figures



PATENTED APR 18 1972

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SHEET 1 OF 2

FIG. 1

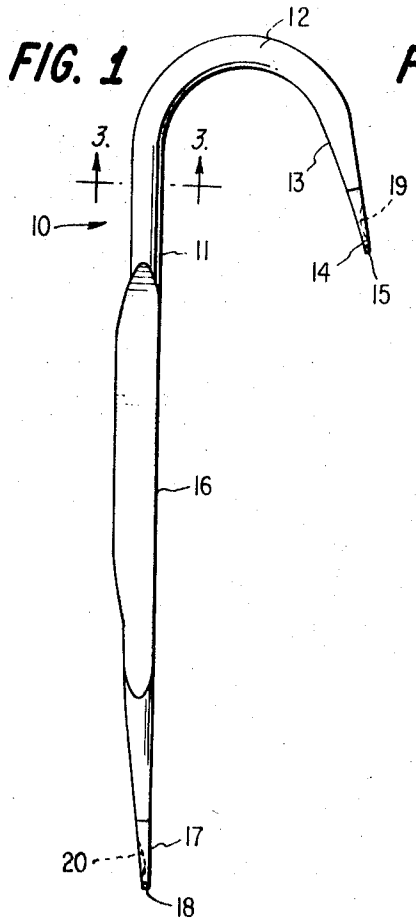


FIG. 2

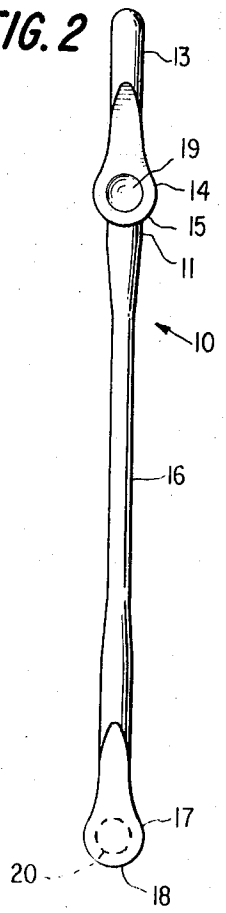


FIG. 3

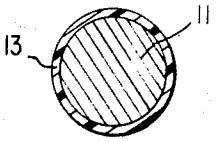
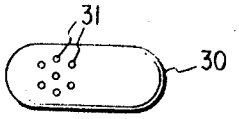


FIG. 4



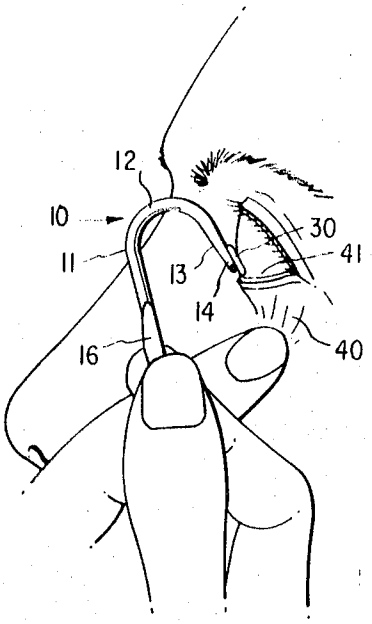


FIG. 5

INVENTOR
RICHARD A NESS

BY Steven D. Goldby
ATTORNEY

FIG. 6

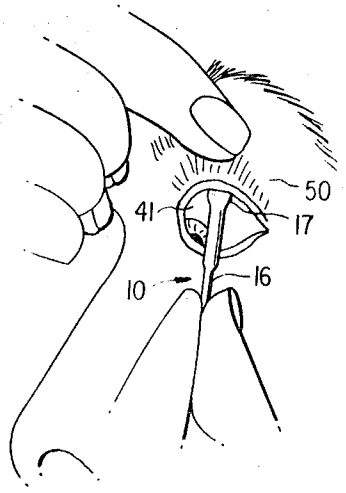


FIG. 7

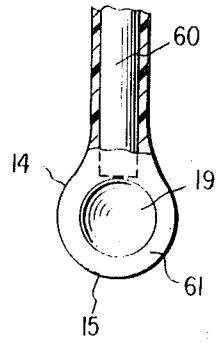
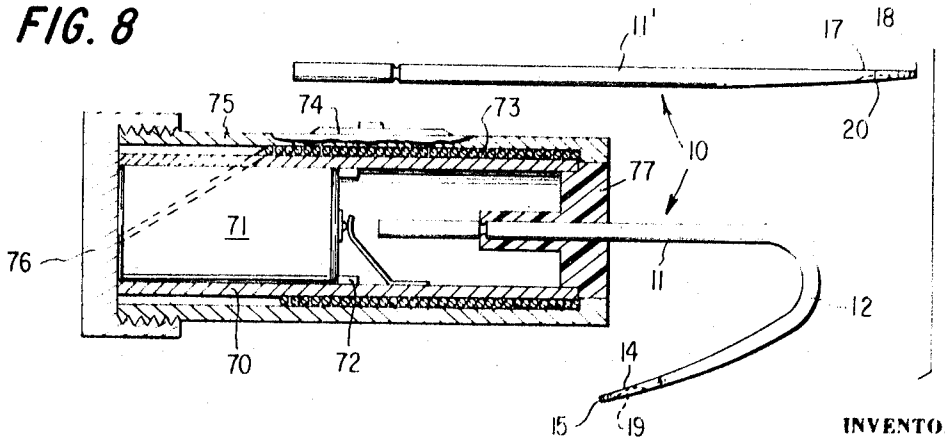


FIG. 8



INVENTOR
RICHARD A. NESS

BY Steven D. Goldby
ATTORNEY

MAGNETIC OPHTHALMIC INSTRUMENT FOR EYE THERAPY

BACKGROUND OF THE INVENTION

The present invention relates to a magnetic ophthalmic instrument for eye therapy and, more especially, to a magnetic instrument for inserting, manipulating, and removing magnetically attractable objects, especially drug dispensing ocular inserts, from in contact with the eyeball.

U. S. Pat. No. 3,416,530 is directed to my invention of a drug dispensing ocular insert that acts as a depot or drug reservoir, retaining and slowly releasing drug to the eye for prolonged periods of time. Such ocular inserts are fabricated of flexible polymeric materials that are biologically inert, non-allergenic, and insoluble in tear liquid. To initiate the therapeutic program, the ocular insert is placed in the cul-de-sac of the conjunctiva between the sclera of the eyeball and the lid, preferably under the lower lid. Since the polymeric material from which the ocular insert is formed is insoluble in tear liquid, it retains its integrity and remains intact during the course of therapy, acting as a reservoir to continuously release drug to the eye and surrounding tissues at a rate which is not affected by dissolution or erosion of the polymeric material. On termination of the therapeutic program, the ocular insert is removed from the cul-de-sac.

To effect insertion or removal of the ocular insert from the cul-de-sac, the aforesaid patent suggests using holders of the type commonly used to insert and remove corneal contact lenses, scleral lenses, artificial eyes and the like. Such holders generally include a minute suction cup for engaging the outer wall of the body. Because of the small size of such ocular inserts, manipulating them by means of a suction cup device is not entirely satisfactory. Moreover, available instruments are not designed for placement in the upper and lower cul-de-sac and are awkward to use.

To permit sure and easy insertion and removal of drug dispensing ocular inserts, it has been found that a magnetically attractable material can be incorporated in the ocular insert and the insert manipulated with a magnetic tool. Such magnetically attractable ocular inserts are further described in copending application Ser. No. 821,468, filed May 2, 1969. As disclosed therein, suitable magnetically attractable materials include metals and metal alloys, especially those of iron. Preferably, the magnetically attractable material is coated with an insoluble biologically inert non-irritating polymeric material prior to incorporation in the ocular insert. In a similar manner, magnetically attractable material can be incorporated into a contact lens or scleral lens to ease insertion and removal of that therapeutic device. Available magnetic instruments have not been designed for insertion and removal of such magnetically attractable objects from the eye and are not entirely satisfactory for this purpose.

BRIEF DESCRIPTION OF THE INVENTION

Accordingly, it is one object of this invention to provide a magnetic ophthalmic instrument for inserting, manipulating, and removing magnetically attractable objects from against the eyeball or cornea.

Another object of this invention is to provide a magnetic instrument for inserting, manipulating, and removing magnetically attractable objects under the lower eyelid or the upper eyelid.

In accomplishing these objects, one feature of this invention resides in an ophthalmic instrument comprising a shank terminating at one end in a curved arm, at least the terminal portion of the curved arm being flat, magnetic, and having a blunt tip. The instrument can be used to insert or remove magnetically attractable objects against the eyeball by attraction of the objects to the flat and magnetic terminal portion of the instrument.

Another feature of this invention resides in such an instrument further including means for electrically generating a magnetic field about the shank to render the shank and the terminal portion magnetic.

Still a further feature of this invention resides in such an instrument wherein the end of the shank remote from the curved arm also terminates in a flat, magnetic terminal portion having a blunt tip.

Other objects, features, and advantages of this invention will become more apparent to those skilled in the art from the detailed description of the invention which follows and from the drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

In the drawings:

FIG. **1** is a side view of the magnetic ophthalmic instrument of the invention.

FIG. **2** is a front view of the magnetic ophthalmic instrument of the invention.

FIG. **3** is a cross-sectional view, taken along the line **3—3'** of FIG. **1**.

FIG. **4** is a front view of the face of a drug dispensing ocular insert having magnetically attractable material incorporated therein.

FIG. **5** is a side view of the upper portion of a human face, illustrating the use of the invention to insert a drug-dispensing ocular insert under the lower eyelid.

FIG. **6** is a three-quarter view of the upper portion of a human face illustrating the use of the invention to retrieve a drug dispensing ocular insert from under the upper eyelid.

FIG. **7** is a fragmentary front view of another embodiment of the magnetic instrument of the invention.

FIG. **8** is a cross-sectional view of an electromagnetic version of the magnetic instrument of the invention.

DETAILED DESCRIPTION OF THE INVENTION

In FIGS. **1** and **2**, generally indicated at **10** is a J-shaped magnetic ophthalmic instrument according to the invention comprised of an elongated shank portion **11** terminating at one end in a curved arm **12**, at least the terminal portion **14** of said curved arm **12** being flat (advantageously a flattened ellipsoid in cross-section) and magnetic, and said terminal portion **14** having a curved marginal outline (advantageously rounded) and blunt tip **15**. The outer face surface of the terminal portion **14** having a curved marginal outline is, at its widest point, preferably wider than the remainder of said curved arm **12**, and said terminal portion **14** of the arm **12** is preferably at an angle less than about 180° to the longitudinal axis of the shank **11**, and even more preferably is at an angle of about 160° to 170° to the longitudinal axis of the said shank **11** (although any angle which will facilitate the insertion, manipulation, and removal of magnetically attractable inserts from against the eyeball will suffice - generally, an angle of less than 180° is preferred so as to avoid interference with the cheek of the user).

The instrument of FIGS. **1** and **2** is also shown as being functional at either end. Thus, the terminal portion **17** of the elongated shank **11** remote from the curved arm **12** is also flat (advantageously a flattened ellipsoid in cross-section) and magnetic, and said terminal portion **17** likewise has a curved marginal outline (advantageously rounded) and blunt tip **18**. The outer face surface of the terminal portion **17** having a curved marginal outline is also at its widest point preferably wider than the shank **11**. While the straight end of the shank of the illustrated device longitudinally continues to a flat terminal portion **17**, it will be appreciated that this is unnecessary and that end of the device can merely be a continuation of the circular cross-section shank. In such case, all manipulation would be with tip **14**. Moreover, on the flattened surfaces of the ends **14** and **17**, and integral therewith, there are defined small concavities **19** and **20**, respectively, which concavities generally correspond and may vary according to the outside or convex curvature of the ocular insert to be inserted. Such concavities **19** and **20** serve to hold the insert in place while inserting in the eye. The instrument of FIGS. **1** and **2** is additionally shown as having a flattened central portion **16** of shank **11**, with the remainder of said shank **11** being substantially circu-

lar in cross-sectional configuration. The reason for the flattening of the shank of the instrument is so that it will not roll in the fingers and will enable the patient to maintain orientation of the device.

In one embodiment, the entire tool **10** is fabricated of a magnetic material, e.g., a ferromagnetic material. Alternatively, only the terminal portion(s) **14** (and **17**) need be magnetic. These can be rendered magnetic by applying a coating of a magnetic material. Still further, the instrument **10** can be rendered magnetic by generating a magnetic field about shank **11**. This can be done using small penlight batteries and an electrical winding (see FIG. **8**). Preferably, the instrument **10** is in the nature of a permanent magnet, and, as shown in FIG. **3**, is covered with a thin coating **13** of inert, tough protective material non-irritating to the eye and surrounding tissue such as Teflon or other plastics and the like, so that it can be sterilized between usage. The coating **13** also serves to protect the instrument against rust or corrosion.

In FIG. **4** there is illustrated a drug dispensing ocular insert **30** for insertion into the cul-de-sac of the conjunctiva between the sclera of the eyeball and either eyelid to dispense drug to the eye over a prolonged period of time. This insert is adapted for convenient insertion, manipulation and removal by using the ophthalmic instrument of the invention by incorporation of a magnetically attractable substance **31** therein. As heretofore mentioned, such inserts are further described in co-pending application, Ser. No. 821,468, filed May 2, 1969, the disclosure of which is hereby incorporated by reference. Such ocular inserts are fabricated of polymers that are insoluble in tear liquid since erosion or dissolution of the insert would interfere with the continuous and controlled release of drug to the eye, rendering the therapeutic program unpredictable. Suitable materials for fabricating the ocular inserts are flexible polymers through which drug will diffuse or be leached by the action of tear liquid at a slow rate.

Any of the drugs used to treat the eye and surrounding tissues can be incorporated in the ocular insert. Also, it is practical to use the eye and surrounding tissues as a point of entry for systemic drugs that enter circulation in the blood stream and produce a pharmacologic response at a site remote from the point of application of the ocular insert. Thus, drugs which will pass through the eye or the tissue surrounding the eye to the blood stream, or will be absorbed from tears in the nasal-lacrimal duct, nasal mucosa, pharynx or gut, but which are not used in therapy of the eye itself, can be incorporated in the ocular insert.

By use of the illustrated ocular insert, the eye is continuously bathed with drug over a particular time span. Normally, the ocular insert will be retained in place for a period of 24 hours, thereby supplying the complete dosage regime for eye therapy over that period of time.

The ocular insert can be fabricated in any convenient shape for comfortable retention in the cul-de-sac. Thus, the marginal outline of the ocular insert can be ellipsoid, bean-shaped, discoid, rectangular, etc. In cross-section, it can be concavo-convex, rectangular, etc. As the ocular insert is flexible and, in use, will assume essentially the configuration of the cul-de-sac, the original shape of the device is not of controlling importance. Dimensions of the device can vary widely. The lower limit on the size of the device is governed by the amount of the particular drug to be supplied to the eye and surrounding tissues to elicit the desired pharmacologic response, as well as by the smallest sized device which conveniently can be inserted and removed from the eye. The upper limit on the size of the device is governed by the limited space within the cul-de-sac that conveniently and comfortably can be filled with an ocular insert. Typically, the ocular insert is 4 to 20 millimeters in length, 1 to 12 millimeters in width, and 0.1 to 1 millimeter in thickness.

As shown, a magnetically attractable material **31**, such as iron or an iron alloy, is incorporated into the ocular insert of the type previously described in an amount sufficient to render the insert magnetically attractable. The magnetically attractable material can be dispersed throughout the ocular insert or can be isolated therein, as at the core.

Magnetically attractable material can be incorporated in the ocular insert in any convenient manner. When the ocular insert is in the form of a polymeric matrix with the drug uniformly distributed therethrough, the magnetically attractable material can be added to the polymer, in liquid form, prior to molding or casting to the final shape. When the ocular insert takes the form of a hollow capsule with drug in the central compartment thereof, the magnetically attractable material can be dispersed throughout the polymeric walls of the insert or can be disposed within the central compartment. For ease of manipulation, the magnetically attractable substance can be localized at the corners of the ocular insert.

In a presently preferred and the illustrated embodiment, the magnetically attractable material is encapsulated with a coating that is insoluble in tear liquid and non-irritating to the eye and surrounding tissues. Use of encapsulated magnetically attractable material prevents any possible irritation to the eye from the foreign matter. Suitable encapsulating materials include silicone rubber, cellulose derivatives such as cellulose ethers and cellulose esters, nylon, polyvinylchloride, polyvinylalcohol, polyvinylacetate, polyvinylpyrrolidone, modified collagen, and other non-irritating polymeric materials. Of course, when the ocular insert is fashioned so that the magnetically attractable material is not disposed on the surface thereof and will not come in direct contact with the eye or surrounding tissues, encapsulation is unnecessary.

Usually, drug dispensing ocular inserts are designed to dispense drugs to the eye over a period of 24 hours. When repeated daily therapy is required, devices must be inserted and removed once a day. By using the improved ocular insert of the said co-pending application in conjunction with the ophthalmic instrument of the present invention, the previously awkward procedure in which the insert was sometimes contaminated by contact with the patient's fingers is eliminated and a sanitary means provided for inserting and removing the insert under aseptic conditions.

FIG. **5** illustrates the use of the ophthalmic instrument **10** of the invention to insert a magnetically attractable drug dispensing ocular insert **30** under the lower eyelid. As shown, the lower eyelid **40** is pulled outwardly to open the cul-de-sac of the conjunctiva between the sclera **41** of the eyeball and lower eyelid, and the ocular insert **30**, which is engaged with the magnetic face of tip **14**, is inserted into said cul-de-sac and manipulated to the proper position with the magnetic instrument **10**. Thereafter, the eyelid is released to close the cul-de-sac and the instrument is disengaged from the ocular insert by a gentle pulling motion. The insert is removed from the cul-de-sac in a similar manner by sweeping the same with the said magnetic instrument.

Similarly, the device **10** can be used to insert or remove magnetically attractable ocular inserts from the cul-de-sac of the conjunctiva between the sclera **41** of the eyeball and upper eyelid **50** by engaging the ocular insert **30** with the magnetic face of tip **17** (see FIG. **6**). Retrieval of a drug dispensing ocular insert from under the upper eyelid **50** is depicted in FIG. **6** by raising the same upwardly and outwardly to open the cul-de-sac and thence by sweeping said cul-de-sac with the magnetic tip **17** of device **10** until the insert is engaged. Thereafter, the instrument, to which the insert is now engaged, is merely withdrawn.

The embodiment of FIG. **7** illustrates that it is entirely possible that the magnetic field be maintained by means of a permanently magnetized rod **60** which is bent in the general shape of the magnetic instrument and then imbedded in an inert, tough plastic or like material **61** non-irritating to the eye and surrounding tissue. Such plastic or like material **61** is either cast or thermo-formed about rod **60** in a mold. The subject instrument has advantages including: (a) The maximum magnetic flux would be brought up to the middle of the face of tip **14** (or **17**) and at the concavity **19** (or **20**); (b) Expensive forging operations are eliminated because the magnetized rod

is uniform throughout (the only manufacturing processes required being bending and cutting); and (c) The magnetized rod being itself imbedded in the inert plastic, will not rust or corrode and the instrument readily lends itself to sterilization. The external geometry of the plastic sheath **61** is of course tantamount to those configurations depicted in FIGS. **1** and **2**.

A representative electromagnetic version of the ophthalmic instrument of the invention is illustrated in FIG. **8** as being comprised of a sheath **70** of iron, steel or other suitable magnetic material, a length of which sheath defines a chamber or case for an ordinary, small pen-light battery **71**. Annular ring **72** provides a resilient stop within the sheath for the said battery **71**. Wrapped around the sheath **70** is a coil of copper windings **73** which is energized or activated by a simple push button type switch **74**. The switch **74** is merely of spring or like type on the side of plastic housing or handle member **75**, into which member **75** the entire above assembly is disposed and is there retained by threaded cap **76** which also biases the battery **71** in place. Operation of the subject device is hence much akin to an ordinary flashlight, with the simple circuitry for energizing the coil via the battery not being shown. An ophthalmic instrument according to the invention thus becomes the core of the electromagnet upon its being placed inside the coil. This is accomplished by providing a top closure member **77** into which the devices **10** according to the invention can be conveniently threaded, snapped or friction fitted so as to extend along the longitudinal axis of the said coil. It will be appreciated that configurations similar to the devices **10** of FIG. **8**, namely, instruments functional at but a single end of the shank, are also within the scope of the invention. In such instances all manipulation would be done with tips **14** and **17**, respectively.

It will also be appreciated that by "ocular insert" as used herein, there is intended to be covered such variations as scleral lenses and corneal contact lenses which have been rendered magnetically attractable, as by incorporating the magnetically attractable material into the periphery of the lens. The electromagnetic version of the invention would be especially useful for inserting and removing the various ocular inserts, particularly contact lenses, the operation being eased since the insert can be disengaged from the instrument by terminating current flow in the coil.

While there have been described and pointed out the fundamental novel features of the invention as applied to the preferred embodiments, those skilled in the art will appreciate that various changes and modifications and omissions from the ophthalmic instrument for eye therapy described herein can be made without departing from the spirit of the invention. It is the intention, therefore, to be limited only by the scope of the claims which follow.

What is claimed is:

1. An ophthalmic instrument for manipulating magnetically attractable objects against the eyeball comprising a shank terminating at one end in a curved arm to provide a generally J-shaped device, at least the terminal portion of said curved arm being flat and magnetic, said terminal portion having a blunt tip, and said flat, magnetic and blunt tipped terminal portion being adapted in marginal outline and cross-section for inserting, manipulating and removing magnetically attractable objects from or in contact with the eyeball by attraction of said objects to said flat, blunt and magnetic terminal portion of said instrument.

2. The ophthalmic instrument as defined in claim **1** wherein the outer face surface of said terminal portion has a curved marginal outline.

3. The ophthalmic instrument as defined in claim **1** wherein the outer face surface of said terminal portion has a curved marginal outline and, at its widest point, is wider than the remainder of said curved arm.

4. The ophthalmic instrument as defined in claim **1** wherein said terminal portion is formed of a magnetic material.

5. The ophthalmic instrument as defined in claim **1** wherein the outer face surface of said terminal portion bears a coating of a magnetic material.

6. The ophthalmic instrument as defined in claim **1** further including means for electrically generating a magnetic field about said shank to render said shank and said terminal portion magnetic.

7. The ophthalmic instrument as defined in claim **1** wherein said terminal portion is bent back about itself at an angle of about 160° to 170° to the longitudinal axis of said shank.

8. The ophthalmic instrument as defined in claim **1** wherein the central portion of said shank is flattened and the remainder of said shank is substantially circular in cross-sectional configuration.

9. The ophthalmic instrument as defined in claim **1** wherein the end of said shank remote from said curved arm terminates in a second flat, magnetic terminal portion having a blunt tip, and said second flat, magnetic and blunt tipped terminal portion also being adapted in marginal outline and cross-section for inserting, manipulating and removing magnetically attractable objects from or in contact with the eyeball by attraction of said objects to said flat, blunt and magnetic second terminal portion of said instrument.

10. The ophthalmic instrument as defined in claim **9** wherein the face surface of said second terminal portion has a curved marginal outline.

11. The ophthalmic instrument as defined in claim **9** wherein the face surface of said second terminal portion has a curved marginal outline and, at its widest point, is wider than said shank.

12. The ophthalmic instrument as defined in claim **9** wherein said second terminal portion is formed of a magnetic material.

13. The ophthalmic instrument as defined in claim **9** wherein one face surface of said second terminal portion bears a coating of a magnetic material.

14. The ophthalmic instrument as defined in claim **9** whereon the flattened surfaces of both terminal portions, and integral therewith, there are defined small concavities, which concavities generally correspond to the outside curvature of the magnetically attractable object to be manipulated.

15. The ophthalmic instrument as defined in claim **9** comprised of a sheath of inert material non-irritating to the eye and surrounding tissue and a core of a permanently magnetized rod imbedded therein and bent in the general shape of the instrument.

16. The ophthalmic instrument as defined in claim **1** whereon the flattened surface of the terminal portion, and integral therewith, there is defined a small concavity, which concavity generally corresponds to the outside curvature of the magnetically attractable object to be manipulated.

17. The ophthalmic instrument as defined in claim **1** comprised of a sheath of inert material non-irritating to the eye and surrounding tissue and a core of a permanently magnetized rod imbedded therein and bent in the general shape of the instrument.

18. The ophthalmic instrument as defined in claim **1** provided with a coating of an inert material non-irritating to the eye and surrounding tissue.

19. An ophthalmic instrument for manipulating magnetically attractable objects against the eyeball comprising a shank of substantially circular cross-sectional configuration having a flattened central portion, said shank terminating at one end in a curved arm, said curved arm having a first flat, terminal portion with a blunt tip, and having an outer face surface with a curved marginal outline, the end of said shank remote from said curved arm terminating in a second flat terminal portion having a blunt tip and a face surface with a curved marginal outline, both of said terminal portions being magnetic, and both of said flat, magnetic and blunt tipped terminal portions being adapted in marginal outline and cross-section for inserting, manipulating and removing magnetically attractable objects from or in contact with the eyeball by attraction of said objects to said flat, blunt and magnetic terminal portions of said instrument.

20. The ophthalmic instrument as defined in claim **19** wherein said terminal portions have face surfaces with a

curved marginal outline and, at their widest point, wider than said curved arm.

21. The ophthalmic instrument as defined in claim 19 wherein the outer face surface of said first terminal portion and one face surface of said second terminal portion bear a coating of a magnetic material.

22. The ophthalmic instrument as defined in claim 19 wherein said first terminal portion is bent back about itself at an angle of about 160° to 170° to the longitudinal axis of said shank.

23. An ophthalmic instrument for manipulating magnetically attractable objects against the eyeball comprising a shank of substantially circular cross-sectional configuration having a flattened central portion, said shank terminating at one end in a curved arm to provide a generally J-shaped device, said curved arm having a first terminal portion bent back about itself at an angle of about 160° to 170° to the longitudinal axis of said shank, said first terminal portion being flat, magnetic, having a blunt tip, and an outer face surface with a curved marginal outline that is wider than the remainder of said curved arm, the end of said shank remote from said curved arm terminating in a second terminal portion which is flat, magnetic, has a blunt tip, and a face surface with a curved marginal outline which is wider than said shank, and both of said flat, magnetic and blunt tipped terminal portions being adapted in marginal outline and cross-section for inserting, manipulating and removing magnetically attractable objects from or in contact with the eyeball by attraction of said objects to said flat, blunt and magnetic terminal portions of said instrument.

24. An ophthalmic instrument for manipulating magnetically attractable objects against the eyeball comprising a shank terminating at one end in a terminal portion which is flat and magnetic, said terminal portion having a blunt tip, whereon the flattened surface of said terminal portion, and integral therewith, there is defined a small concavity, which concavity generally corresponds to the outside curvature of the magnetically attractable object to be manipulated, and said flat, magnetic and blunt tipped terminal portion being adapted in marginal outline and cross-section for inserting, manipulating and removing magnetically attractable objects from or in contact with the eyeball by attraction of said objects to said flat, blunt and magnetic terminal portion of said instrument.

25. The ophthalmic instrument as defined in claim 24 further including means for electrically generating a magnetic field about said shank to render said shank and said terminal portion magnetic.

26. The ophthalmic instrument as defined in claim 24 comprised of a sheath of inert material non-irritating to the eye and surrounding tissue and a core of a permanently magnetized rod imbedded therein and bent in the general shape of the instrument.

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