

- [54] **RADIOLOGICAL DIAGNOSTIC METHOD**
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[51] **Int. Cl.** **A61b 5/00**
[58] **Field of Search** 128/2 A, 2 R, 2.05 R;
250/65 R

[56] **References Cited**
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[57] **ABSTRACT**

A radiological diagnostic method is provided in which a radiopaque ferrofluid is injected into a body system which is to be studied, such as the subarachnoid space surrounding the spinal cord. The ferrofluid is then transferred through the body system by applying a magnetic force to the ferrofluid. The portions of the body system of particular interest are radiographically or fluoroscopically examined while the ferrofluid is present in these areas. The ferrofluid is thereafter removed by drawing it back to the point of introduction and removing it from the body system. The diagnostic method of this invention is especially useful in myelographic studies.

11 Claims, 6 Drawing Figures

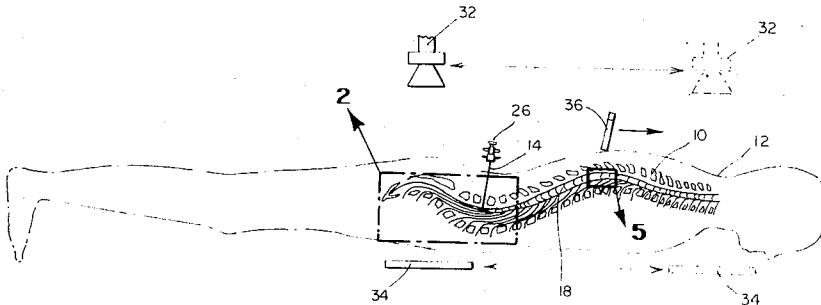


Fig. 4

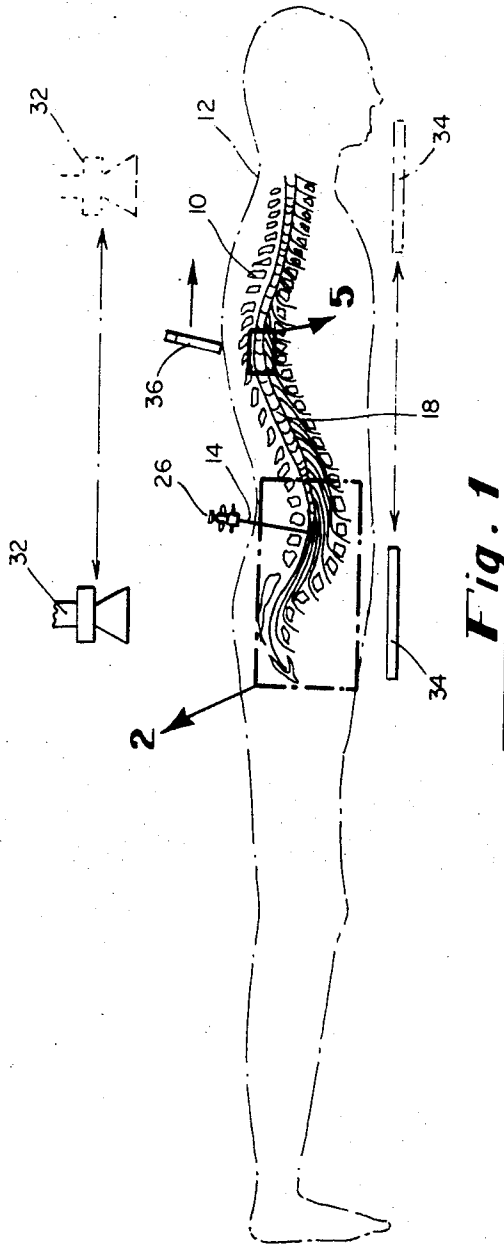
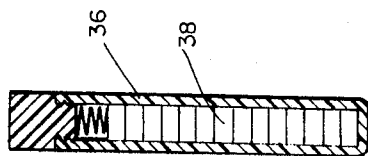


Fig. 1

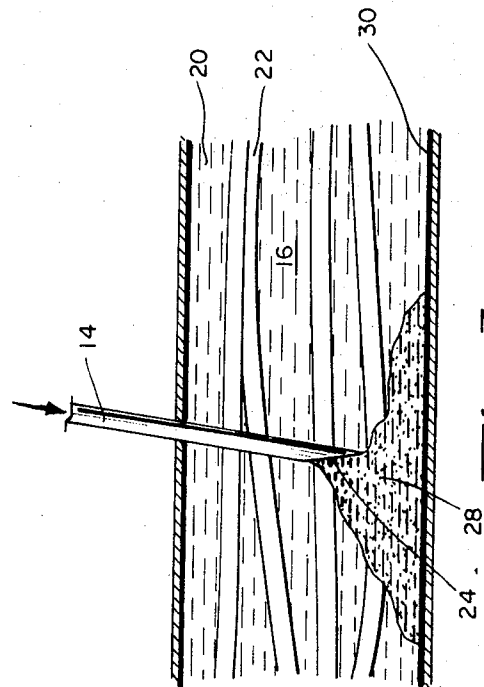


Fig. 3

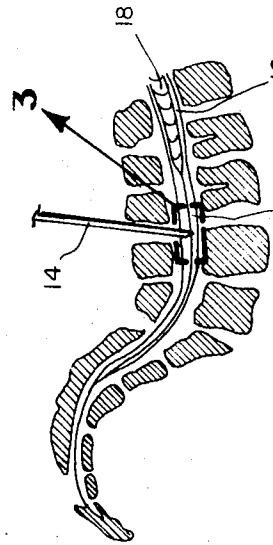


Fig. 2

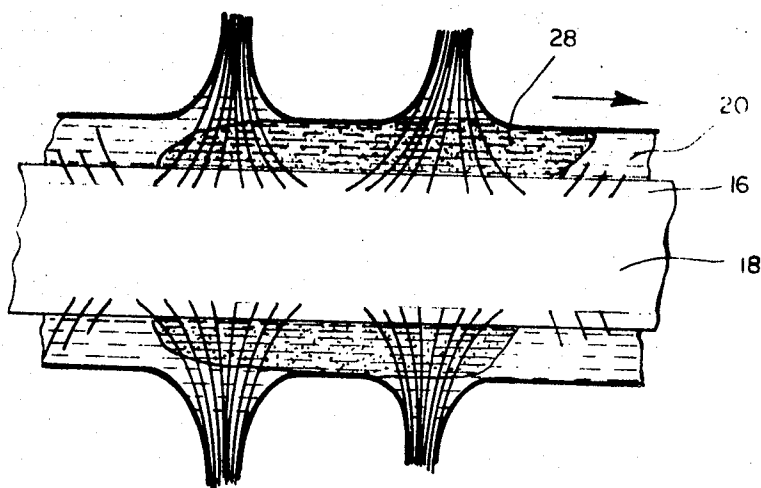


Fig. 5

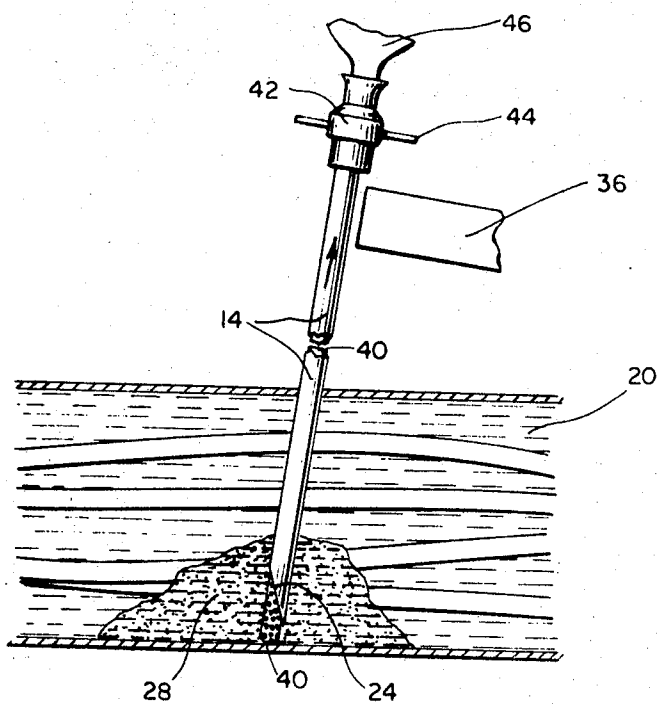


Fig. 6

RADIOLOGICAL DIAGNOSTIC METHOD

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention is concerned with a radiological diagnostic method.

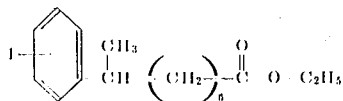
2. Description of the Prior Art

Radiological diagnostic procedures are widely used in the medical field to detect various abnormalities of the body, such as broken bones, ulcers, tumors, and the like. In order to obtain satisfactory results with radiological procedures, it is necessary to have a substantial difference in the radiopaqueness of the area which is desired to be examined and the immediate surrounding areas of the body. When a radiological study is made, to determine for example, if one of the long bones of the body is broken no particular problems are encountered, in that bone is relatively radiopaque as compared to the surrounding soft tissues.

However, when a radiological study is made of certain parts of the body, there is often an insufficient amount of contrast in the radiopaqueness of the areas to be studied and the surrounding tissues, or, the area to be examined is covered by a relatively radiopaque material which shields the desired area of study. A typical situation of this type is when a myelogram is performed, wherein the subarachnoid space surrounding the spinal cord is X-rayed to determine if any abnormalities distorting its normal pattern are present, such as tumors, herniated discs, osteophytic spurs, abscesses, and the like. Because of the presence of the protective relatively radiopaque shield of vertebrae about the spinal column and the relative similarity and lack of radiopaqueness of the elements comprising the soft tissues of the spinal column, such as the spinal cord, and the pia, arachnoid and dura membranes, it is necessary to inject a radiopaque material into the spinal column to increase the radiopaqueness of the subarachnoid space.

Various materials have heretofore been suggested to increase radiopaqueness when conducting myelographic studies. One such method was to inject a gas such as air into the spinal column to replace part of the spinal fluid. This method has proven to be highly unsatisfactory because the patient is subjected to considerable pain as a result of the injection of the gaseous material, and in addition, the relative degree of radiopacity is at best only marginal.

An additional method which has been suggested, is to inject radiopaque liquids into the spinal column. A typical type of compound which is used for this purpose is the compound of the formula



One of the problems encountered with the injection of such radiopaque liquids heretofore suggested was that the compounds, for clinical reasons, should be completely removed after the radiological examination is completed. In actual practice, however, it has been found that it is virtually impossible to completely remove all of the injected compound from the spinal column. It is believed that the residual amounts of these radiopaque materials are a definite contributory factor

in causing the highly painful condition known as adhesive arachnoiditis.

A common technical problem usually encountered when using either gases or conventional radiopaque liquids is that it is difficult to move and accurately position the injected material in the desired location required for the radiological examination. For example, in myelography, the radiopaque agent, whether it is gas or a liquid, is normally injected into the low lumbar subarachnoid space, that is, the portion of the spinal column which is below the lower terminal end of the spinal cord in order to avoid injury to the spinal cord itself. A myelogram, however, generally involves a study of the spinal cord and the surrounding tissues. For this reason, the injected material must be moved up the spinal column to the desired areas of study.

Using the prior art techniques this was accomplished by employing only the difference in the specific gravity of the injected material and the normal body fluid of the body system being evaluated. The relative body position of the patient is changed so as to facilitate the movement of the injected material. The gases which are injected are hyperbaric as compared to spinal fluid which has about the specific gravity of saline. The liquids, on the other hand, are hyperbaric as compared to spinal fluid. To move the injected material from one position to another, requires that the body of the patient be tilted to cause the material to flow from one part of the spinal column to another. Due to the difference between specific gravities of the injected material and spinal fluid, the patient is generally raised or lowered on a tilt table especially designed for this purpose. However, even using this specialized apparatus, the process is at best, uncomfortable and often quite painful to the patient, especially in cases where the patient has an acute spinal abnormality. It should be further noted, that in certain situations, it is even necessary to rotate the patient approximately 180° with respect to the normal erect position so that his head is in a downward position. This of course, is highly uncomfortable and in some cases, highly dangerous.

The gravitational technique for moving the injected material throughout the spinal column has the further disadvantage that the injected substance often breaks into separate smaller globules and thereby becomes ineffective as a radiopaque agent. Once the material separates, it is difficult, to recombine the material so as to effectively conduct radiological study. An additional problem that is encountered is that when the radiopaque material is positioned by gravitational methods it is often difficult to maintain the radiopaque material at the desired location for sufficient time to adequately expose X-rays and obtain an accurate study. This is due in part to the natural curvature of the spine, which promotes rapid flow of the radiopaque material along certain areas of the spinal column.

It is accordingly an object of this invention to overcome the aforementioned problems and difficulties of the prior art.

It is still a further object of this invention to provide an improved radiological diagnostic method which is safer for the patient, and which can be more effectively utilized by a radiologist to achieve more accurate studies.

Other objects and advantages of this invention will become further apparent hereafter from a continued

reading of the specification and study of the attached drawings.

BRIEF SUMMARY OF THE INVENTION

The objects of this invention have been achieved by providing a radiological diagnostic method comprised of injecting a radiopaque ferrofluid into the body system to be radiologically studied; moving the ferrofluid with a magnet to the particular location desired to be examined, and after the study is completed, removing the ferrofluid from the body system.

BRIEF DESCRIPTION OF THE DRAWING

FIG. 1 is a schematic illustration of a body which is being radiographically examined in accordance with the method of this invention. The spinal column of the body is shown in full lines.

FIG. 2 is an enlarged illustration taken as indicated by the dotted area 2 of FIG. 1.

FIG. 3 is an enlarged illustration of the dotted area 3 of FIG. 2.

FIG. 4 is an illustration in cross section of a magnet which is especially useful for employment in the method of the present invention.

FIG. 5 is an enlarged illustration of the area 5 of FIG. 1.

FIG. 6 is an illustration of the removal of the ferrofluid from the spinal column in accordance with the teachings of this invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

In describing the method of this invention, particular reference will be made to the use of the method of this invention for the radiological examination of the spinal column in order to facilitate the explanation of the invention. However, it should be appreciated that the method of the present invention is not limited to radiological examination of the subarachnoid space of the spinal column and can be also used to examine various other areas of the spinal column and body systems wherein there is a relatively slow flow of fluids and also systems which have mucous linings. These systems include among others, the respiratory tract, the upper gastrointestinal system, the genitourinary tract and the ventricular system of the brain.

In the method of this invention ferrofluids are used as the radiopaque contrast means. Ferrofluids are a relatively new class of fluids. These fluids are commercially available or can be prepared by known methods. Ferrofluids are colloidal dispersions of single domain ferromagnetic particles. The ferrofluids as a class are unique, in that it is possible by inducing a magnetic force to move the ferrofluids in direct response to the magnetic force. The magnetic response of the ferrofluids is due to the coupling of the individual ferromagnetic particles with a substantial volume of a surrounding carrier liquid. The magnetic force, when applied to the ferrofluid, attracts the enveloped ferromagnetic particles together with the associated liquid carrier so that the entire liquid mass is drawn as a unit by the magnetic force.

The method of preparing ferrofluids is known to those skilled in the art, however, to facilitate an explanation of this invention the process will be briefly described. Since most inorganic magnetic solids are characteristically insoluble in common liquids, the coupling

of magnetic particles with the carrier liquid is accomplished by using a mordant-like material, which is initially applied to the particles of the magnetic material. The mordant-like material, or as it is often referred to as the stabilizer, has the ability to be both adsorbed onto the surface of the magnetic particles and also to solvate the carrier liquid. A typical compound of this type is oleic acid. The ferromagnetic particles which are used are relatively small being colloidal in size with diameters in the range of about 10 to 300 Å (Angstroms) being most desirable. It should be appreciated that the term ferrofluid as utilized in this application is not limited to ferroliquids which contain iron, but is generic to all fluids which exhibit the above noted properties including liquids which contain metals other than iron which can effectively be moved by a magnetic force, such as chromium.

The selection of the type and amount of the carrier liquid which is used in the method of the present invention is highly important. In the manufacture of the ferrofluids, if an excess amount of carrier liquid is employed or if thereafter additional amount of carrier liquid is added to the ferrofluid system, a phase separation will occur which destroys the ferrofluid properties. On the other hand, if an insufficient amount of carrier liquid is employed in the manufacture of ferrofluids or if a portion of the carrier liquid is removed from the ferrofluid, the ferromagnetic particles will agglomerate and the ferrofluid properties will likewise be destroyed.

In view of the relative critical balance between the ratio of the amount of the ferromagnetic particles and the liquid carrier in the ferrofluid, it is important to select a ferrofluid which will not be adversely effected when used in the method of the present invention. Furthermore, the ferrofluids as a whole and the liquid carrier in particular, must be physiologically inert.

The carrier liquids which are generally employed to make conventional ferrofluids are for example, water, lower aliphatic hydrocarbons, and halogenated aliphatic hydrocarbons. It can be readily appreciated that the ferrofluids having water as a carrier liquid would be unsuitable in the method of the present invention, in that, the water normally found in body fluids would blend with the ferrofluids and thereby dilute the ferrofluids, destroying the properties by dilution as noted above. On the other hand, certain commonly used carriers are absorbed by the body, and consequently, the absorption would destroy the ferrofluids by concentration of the ferrofluids to a point where the ferromagnetic particles would agglomerate. It has been found, however, that certain classes of liquid carriers can be employed which have a broad range of applicability in the method of the present invention. Particular attention is directed to the halogenated aliphatic hydrocarbons especially the perfluorinated aliphatic hydrocarbons.

In order to more clearly explain the method of the present invention, specific attention will be directed to the drawings which show the method of this invention used for either radiographically or fluoroscopically examining the spinal column 10 of a patient 12. A sterile ferrofluid is prepared having a suitable liquid carrier such as a ferrofluid having a perfluorinated aliphatic hydrocarbon liquid carrier and iron ferromagnetic particles. Sterile procedures are followed as is customary in conventional lumbar punctures. An 18 gauge lumbar puncture needle 14 is inserted between the third and

fourth lumbar vertebrae into the subarachnoid space 16 of the cauda equina portion of the spinal column 10. The cauda equina is that portion of the spinal cord which continues as individual nerves extending beyond the spinal cord proper 18. The cauda equina is surrounded by spinal fluid 20 and composed of distal nerve ends 22. The bevel 24 of the needle 14 is positioned in about the center of the cross sectional area of the subarachnoid space of the cauda equina. The stylet 26 is then removed and a predetermined amount, for example, 3 to 12 cc of spinal fluid is aspirated from the spinal column 10. A syringe (not shown) is used to inject approximately the same volume of ferrofluid 28 as the amount of spinal fluid removed into the cauda equina area of the subarachnoid space 16. The stylet 26 is reinserted into the needle 26 and a sterile dressing is placed over the needle assembly.

As can be seen in FIG. 3, the ferrofluid 28 is hyperbaric as compared to the surrounding spinal fluid 20 and accordingly tends to settle to the lower side of the cauda equina in contact with the arachnoid membrane. The patient is now ready for the X-ray examination. The X-ray examination can be either a radiographic examination or a fluoroscopic examination depending upon the particular type of test results desired, but are usually used in combination. However, because of the advantages of the present method, the radiographic method requires less patient radiation exposure thus increasing patient safety.

As shown in FIG. 1, the patient either during or immediately after the lumbar puncture is placed on a conventional X-ray table (not shown), over which there is a moveable X-ray tube 32. A photographic plate 34 is positioned under the patient directly below the X-ray camera for radiographic examinations. The photographic plates are exposed in the conventional manner. In the event that it is desired to make a fluoroscopic examination, the radiographic equipment would be replaced with the appropriate fluoroscopic or image intensification equipment.

Except in somewhat unusual cases, the radiologist is not particularly interested in the immediate area in which the ferrofluid 28 is injected. Accordingly, it is necessary to transfer the radiopaque ferrofluid up or down the spinal column 10 through the subarachnoid space 16 to the area which is desired to be studied.

In accordance with the present invention, the ferrofluid 28 is transferred not by gravity as in the prior art, but is moved by the use of magnetic force along the spinal column to the location desired to be studied, and if required, the ferrofluid can be maintained in this location until the radiological studies are completed. The effects of moving the ferrofluid can be best seen in the FIGS. 1 and 5, wherein the ferrofluid 28 has been drawn from the cauda equina area of the spinal column 10 to the high point in the spinal curve. This part of the spinal column is generally one of the most difficult areas to X-ray. However, using the process of the present invention, the ferrofluid can readily be maintained in this area until the radiographic examination of the area is completed.

The magnet which is used to draw the ferrofluid 28 through the subarachnoid space, can be selected from a variety of permanent and temporary magnets. The magnets can be made of iron, nickel, cobalt and alloys of these metals as well as alloys with aluminum such as Al-Ni-Co, rare earth metals and so forth.

The amount of magnetic force normally required to be applied to the ferrofluid 28 has been found to be about 5,000 to 10,000 Gauss. An electrically energized magnet can be used to create this amount of magnetic energy without endangering the patient, but requires the use of relatively expensive and bulky equipment which is undesirable.

It has been found that a highly effective and compact type of permanent magnet 36 for use in the method of this invention are the rare earth magnets, and particularly the samarium-cobalt magnets. These magnets 36 are made from discs 38 of a samarium-cobalt alloy. The discs 38 are stacked in a suitable container made from a plastic material. A magnet 36 of this type which is about 1 inch in diameter and about 5 inches long can produce a magnetic field strength of up to about 10,000 Gauss which is adequate for use in the method of this invention. Further, it should be noted, that the magnet 36 can be held in the hand of the radiologist and does not require the use of a separate power supply to operate it. Using the samarium-cobalt magnet 36 the ferrofluid 28 is readily drawn through the subarachnoid space 16 to the desired position. It should be carefully noted that the patient 10 is not required to be moved during the entire procedure.

Furthermore, the ferrofluid 28 can be drawn repeatedly up and down the spinal column as required without causing any discomfort or damage to the patient. A very important advantage of this invention, in addition to the relative mobility of the radiopaque material within the spinal column, is a fact that the ferrofluid 28 can be held stationary in an area of the spinal column for extensive studies of the area.

A still further advantage of this invention is that the ferrofluid 28 does not tend to separate like the radiopaque materials heretofore used. Even if the ferrofluid does inadvertently separate into separate sections, it can readily be recombined by drawing the separate portions together with the magnet.

When the radiographic or fluoroscopic study is completed, the ferrofluid is removed in a highly efficient manner which was not heretofore available using the prior art radiopaque materials. As shown in FIG. 6, the ferrofluid is drawn by the magnet 36 back to the place where it was initially introduced. In accordance with the preferred embodiment of this invention the original stylet 26 is removed, and an insert needle composed of a magnetic metal having a round, smooth, perforated tip is inserted in place of the stylet 26. When an 18 gauge needle is employed for the initial injection with an ID 0.033 inches, the insert needle 40 which is inserted will be at least 21 gauge. At the opposite terminal end from the tip of the hollow needle 40 there is a hub 42 which includes a lock 44 which engages the hub of the needle 14. The hollow needle 40 likewise includes a hub to which a syringe 46 is attached.

When withdrawing the ferrofluid 28 the hollow tubular insert needle 40 is magnetized with the magnet 36. The ferrofluid 28 is attracted to the magnetized perforated tip of the hollow needle and is drawn up the hollow needle with the syringe 46. The insert needle has two principal functions. Initially, it is made of a magnetizable metal which assists in the removal of the ferrofluid from the spinal column. Secondly, it should be noted, that when inserted, the tip of the insert needle 40 shields the sharp beveled edge 24 so that the lumbar puncture needle 14 does not accidentally puncture the

distal arachnoid and dural membranes during removal of the ferrofluid. It has been found that as opposed to the conventional method heretofore used, that in accordance with the method of the present invention, all of the ferrofluid can be effectively removed without much difficulty using the process of the present invention.

As is indicated above, the method of the present invention is not limited to radiological examinations of the spinal column but can be used with other body systems wherein there is a relatively slow flow of fluids or which have a mucous lining. The technique employed would be modified according to the particular body system involved. For example, if the ferrofluids were used in place of the conventional barium compounds for purposes of making studies of the upper gastrointestinal tract, the ferrofluid would be introduced by means of a tube or the like which contained a magnetizable element such as a wire or the like, which would assist in the removal of the ferrofluid from the gastrointestinal system after completion of the test. It of course, would be possible to simply allow the ferrofluid to remain in the gastrointestinal system and be expelled by the normal bodily function since the ferrofluids employed are biologically inert. When using the technique of the present invention with the genitourinary tract the method employed would generally consist of using a catheter for the purpose of inserting the ferrofluid into the appropriate organ such as the bladder, kidneys or the like. The catheter should likewise contain a wire or the like that can be magnetized, so as to assist in drawing the ferrofluid toward the catheter upon completion of the radiographic or fluoroscopic examination.

I claim:

1. The method for radiologically examining a body system having an internal area which contains a fluid which is relatively static or which has a mucous lining, said method comprising inserting into said area a given amount of a radiopaque ferrofluid comprised of ferromagnetic domain particles having a diameter of from about 10-300 Å which are enveloped with a physiologically inert liquid carrier which is insoluble and immiscible with said fluid and mucous, said given amount being an amount sufficient to provide an effective contrast in radiopaqueness for a radiological examination; radiological examining said body system, and thereafter removing said ferrofluid from said body system by applying a magnetic force to an extraction means inserted into said area sufficient to magnetically attract said ferrofluid to said extraction means and withdrawing said ferrofluid with said extraction means.

2. The method according to claim 1 wherein the amount of ferrofluid inserted is less than the volume of

the area and wherein the ferrofluid is moved from the point of introduction to a portion of said area by applying a magnetic force to said ferrofluid.

3. The method according to claim 1 wherein the amount of magnetic force delivered to said ferrofluid is from about 5,000-10,000 Gauss.

4. The method according to claim 1 wherein said magnetic force is provided by a permanent magnet comprised of a member selected from the group consisting of a rare earth metal, nickel, cobalt, alloys thereof and alloys with aluminum.

5. The method according to claim 4 wherein said magnet is a samarium-cobalt magnet.

6. The method according to claim 1 wherein said liquid carrier is a fluorinated lower aliphatic hydrocarbon.

7. The method according to claim 1 for radiological examining of the spinal column comprising the steps of inserting a lumbar puncture needle into the subarachnoid space; injecting said given amount of said ferrofluid through said lumbar puncture needle into the subarachnoid space; moving said ferrofluid from the point of insertion through the subarachnoid space by applying a magnetic force of about 5,000-10,000 Gauss to said ferrofluid to transfer said ferrofluid to a section of said area to be radiologically studied; radiologically examining said section; thereafter moving said ferrofluid back to the point of insertion and withdrawing it through said lumbar puncture needle.

8. The method according to claim 7 wherein the ferrofluid is injected into the subarachnoid space surrounding the cauda equina.

9. The method according to claim 7 wherein the magnetic force is provided by a permanent magnet made of a member selected from the group consisting of a rare earth metal, nickel, cobalt, alloys thereof and alloys with aluminum.

10. The method according to claim 9 wherein the magnet is a samarium-cobalt magnet.

11. The method according to claim 7 wherein the lumbar puncture needle has a given ID, a given length and a sharpened bevel at a terminal end thereof, within which an insert needle made of a magnetizable metal having an OD less than said given ID, a length greater than said given length, and a smooth, round, perforated tip is inserted after insertion of the lumbar puncture needle, into the subarachnoid space with tip of the insert needle extending past the bevel of the lumbar puncture needle and thereafter the insert needle is magnetized to attract the ferrofluid to the tip of the insert needle through which the ferrofluid is removed after completion of the radiological examination.

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