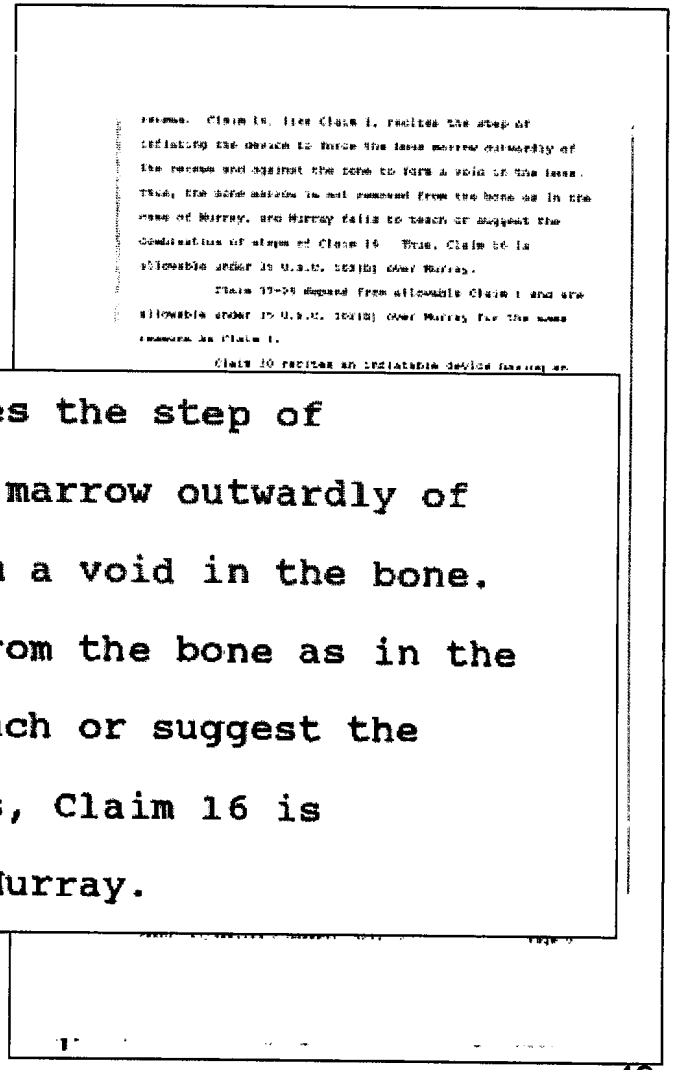
The Claims of the '404 and '888 Patents Require a Balloon

Prosecution History:



recess. Claim 16, like Claim 1, recites the step of inflating the device to force the bone marrow outwardly of the recess and against the bone to form a void in the bone. Thus, the bone marrow is not removed from the bone as in the case of Murray, and Murray fails to teach or suggest the combination of steps of Claim 16. Thus, Claim 16 is allowable under 35 U.S.C. 102(b) over Murray.

See Ex. G at KY 228859

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The Claims of the '404 and '888 Patents Require a Balloon

Claims 1 and 16 of the '888 Patent, as amended November 28, 1989:

1. (Amended) A method of fixation of a fracture or impending fracture of an osteoporotic bone having osteoporotic bone marrow therein comprising:

forming a passage in the bone marrow;

[increasing] compacting the bone marrow to increase the volume of said passage and

filling the passage with a flowable material capable of setting to a hardened condition.

16. (Amended) A method of fixation of an osteoporotic fracture of a bone containing bone marrow therein comprising:

drilling said bone to form a passage therein;

inflating the device in the passage to increase the volume thereof and to force the osteoporotic bone marrow outwardly of the passage and against the bone to form a void in the bone; and

filling the void in the bone with a flowable material capable of setting to a hardened condition.

See Ex. G at KY 228856-57

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The Claims of the '404 and '888 Patents Require a Balloon

Extrinsic Evidence – confirms DOT's interpretation:

- Inventor Testimony
- The asserted '043 Patent

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The Claims of the '404 and '888 Patents Require a Balloon

Dr. Mark Reiley's Testimony:

Q. . . . I would just like to know what you consider the invention to be?
A. The invention is a means of percutaneously accessing -- check that. Entering a vertebral body or any cancellous bone that's deformed and crushing the inside bone and elevating the lids or the joint surface of whatever bone you're working with and making the cavity and deflating the balloon, pulling it out and filling it with cement.
Q. Just want to -- that's fine. When you said it is entering a vertebral body that's deformed and crushing the inside of the bone, I assume -- and then deflating the balloon, I assume that the means for doing that is by blowing up a balloon?
A. Yes.
Q. And that's what's described in the patent?
A. Yes.

See Ex. M, Deposition Tr. of Mark Reiley, M.D., November 3, 2004, at pp. 22-23

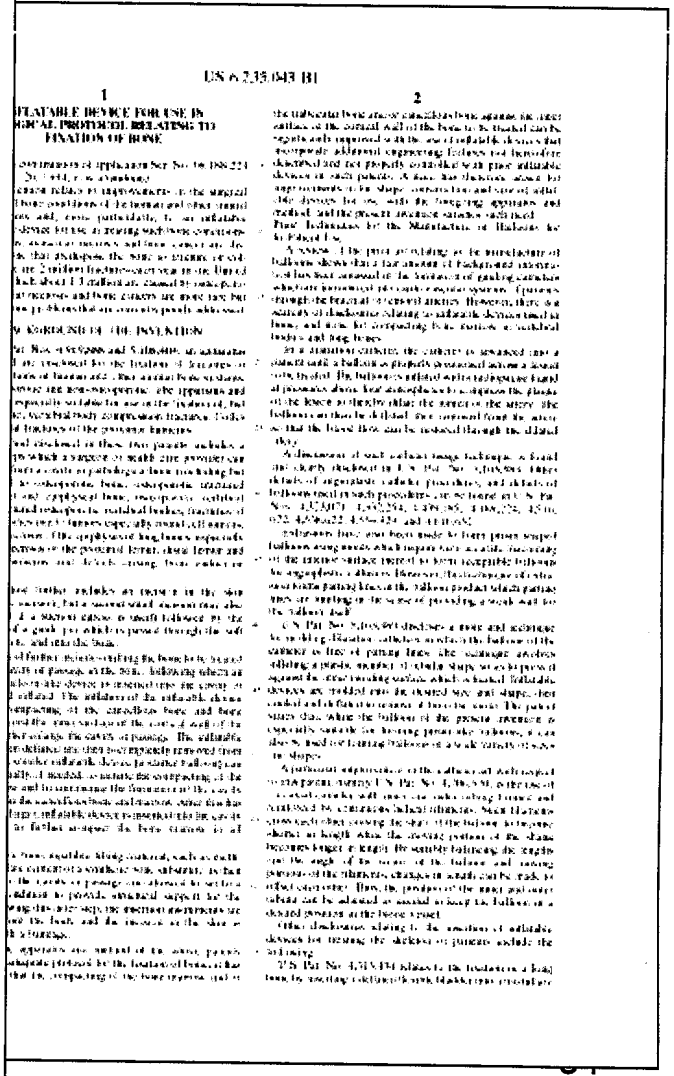
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THE ASSERTED '043 IMPROVEMENT PATENT FURTHER CONFIRMS THAT THE '888 AND '404 REQUIRE A BALLOON

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The '043 Patent "Background of the Invention" Section Confirms that the '888 and '404 Patents Require a Balloon

In U.S. Pat. Nos. 4,969,888 and 5,108,404 an apparatus and method are disclosed for the fixation of fractures. . . .The method further includes drilling bone to be treated to form a cavity or passage in the bone, following which an inflatable balloon-like device is inserted into the cavity or passage and inflated. The inflation of the inflatable device causes a compacting of the cancellous bone and bone marrow against the inner surface of the cortical wall of the bone to further enlarge the cavity or passage. . . .After this has occurred, a larger, inflatable device is inserted into the cavity or passage to further compact the bone marrow in all directions.



US 6,235,043 B1

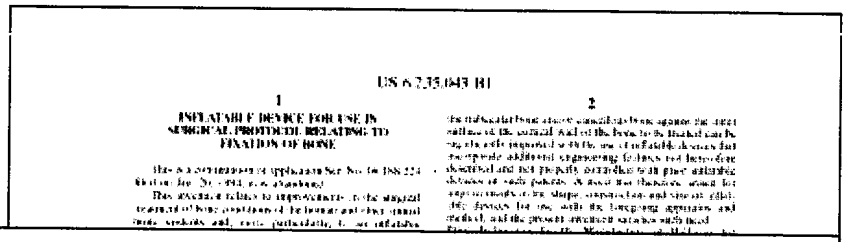
1

INFLATABLE DEVICE FOR USE IN SURGICAL PROTOCOL RELATING TO FIXATION OF BONE

2

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The '043 Patent "Background of the Invention" Section Confirms that the '888 and '404 Patents Require a Balloon



US 6,235,043 B1

1

INFLATABLE DEVICE FOR USE IN SURGICAL PROTOCOL RELATING TO FIXATION OF BONE

2

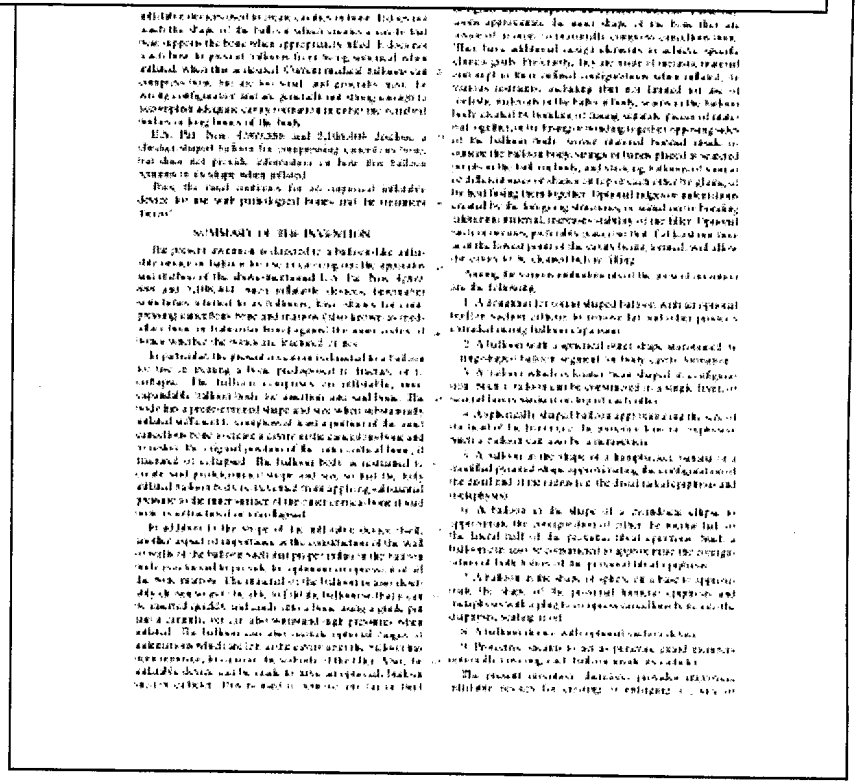
the trabecular bone and/or cancellous bone against the inner surface of the cortical wall of the bone to be treated can be significantly improved with the use of inflatable devices that incorporate additional engineering features not heretofore described and not properly controlled with prior inflatable devices in such patents. A need has therefore arisen for improvements in the shape, construction and size of inflatable devices for use with the foregoing apparatus and method, and the present invention satisfies such need.

Prior Techniques for the Manufacture of Balloons for In-Patient Use

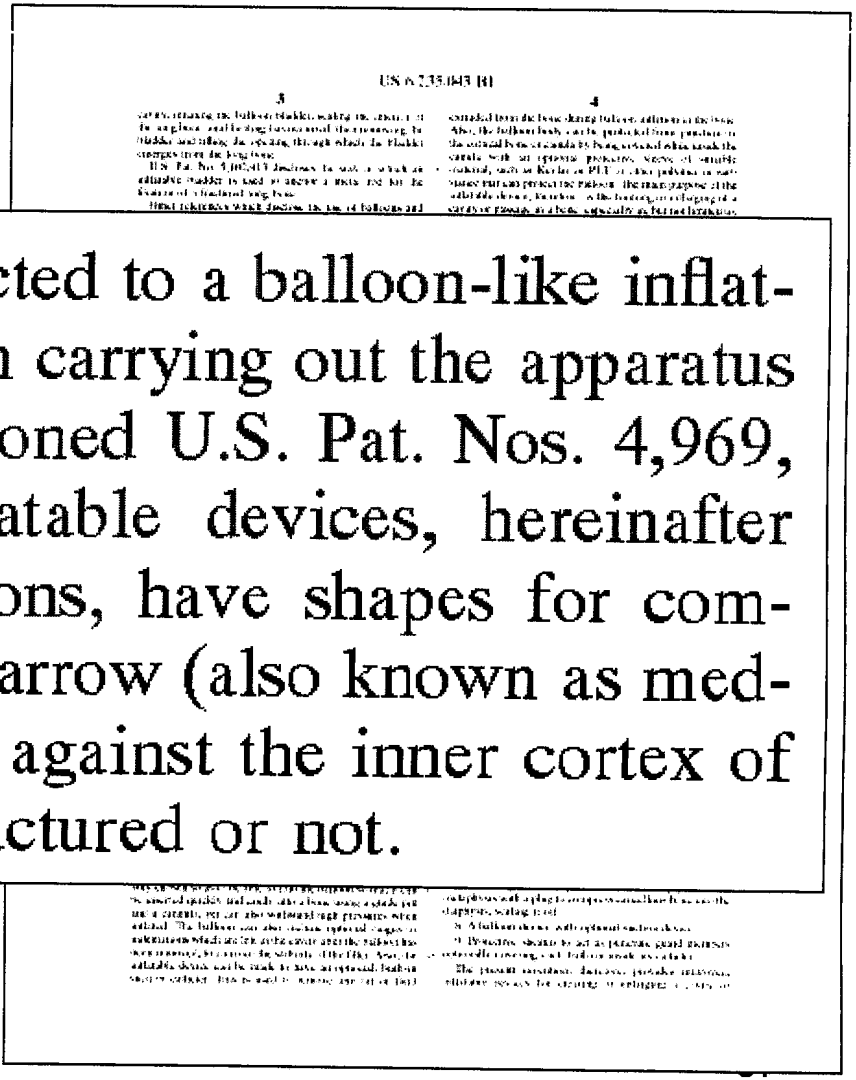
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The '043 Patent "Background of the Invention" Section Confirms that the '888 and '404 Patents Require a Balloon

U.S. Pat. Nos. 4,969,888 and 5,108,404 disclose a checker-shaped balloon for compressing cancellous bone, but does not provide information on how this balloon remains in its shape when inflated.



The '043 Patent "Summary of the Invention" Section Confirms that the '888 and '404 Patents Require a Balloon



The present invention is directed to a balloon-like inflatable device or balloon for use in carrying out the apparatus and method of the above-mentioned U.S. Pat. Nos. 4,969,888 and 5,108,404. Such inflatable devices, hereinafter sometimes referred to as balloons, have shapes for compressing cancellous bone and marrow (also known as medullary bone or trabecular bone) against the inner cortex of bones whether the bones are fractured or not.

DOT IS NOT READING LIMITIATIONS FROM THE SPECIFICATION INTO THE CLAIMS

- The Specification discloses three embodiments for using the patented method – vertebrae, wrist and leg
- An argument that the claims did not cover using the method to fix an arm fracture would be an example of improperly reading limitations into the claims
- The patents define the invention as the use of an inflatable device; under controlling Federal Circuit law that is not improperly importing limitations into the claims

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