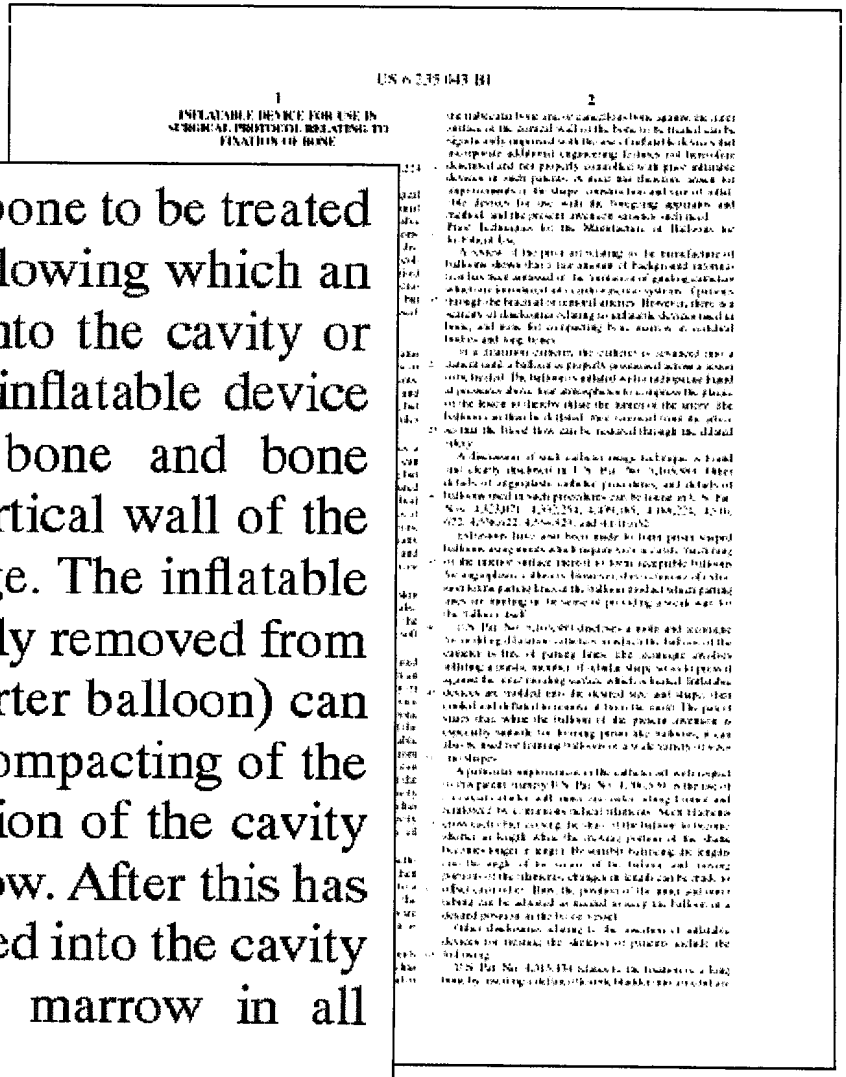
All Claims of the '043 Patent Require a Balloon

The Background of Invention:

The method further includes drilling the 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. The inflatable device is then deflated and then is completely removed from the bone. A smaller inflatable device (a starter balloon) can be used initially, if needed, to initiate the compacting of the bone marrow and to commence the formation of the cavity or passage in the cancellous bone and marrow. After this has occurred, a larger, inflatable device is inserted into the cavity or passage to further compact the bone marrow in all directions.


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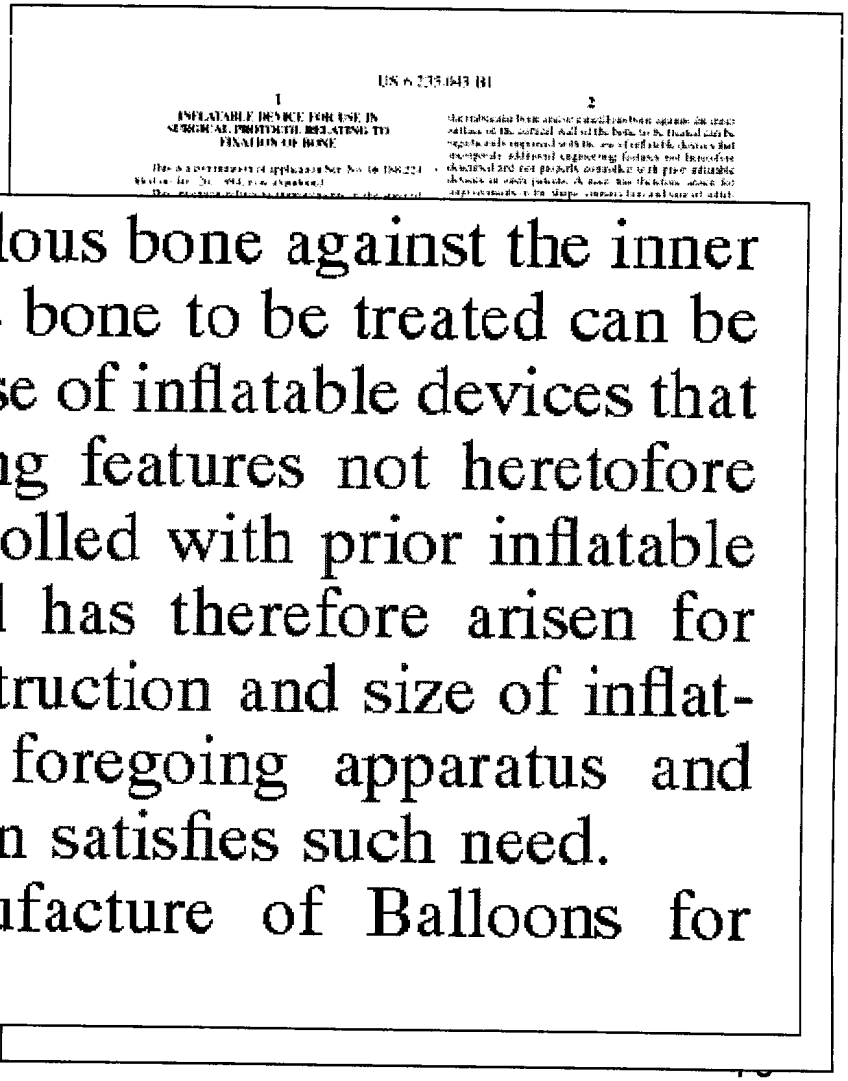
1

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

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All Claims of the '043 Patent Require a Balloon

The Background of Invention:

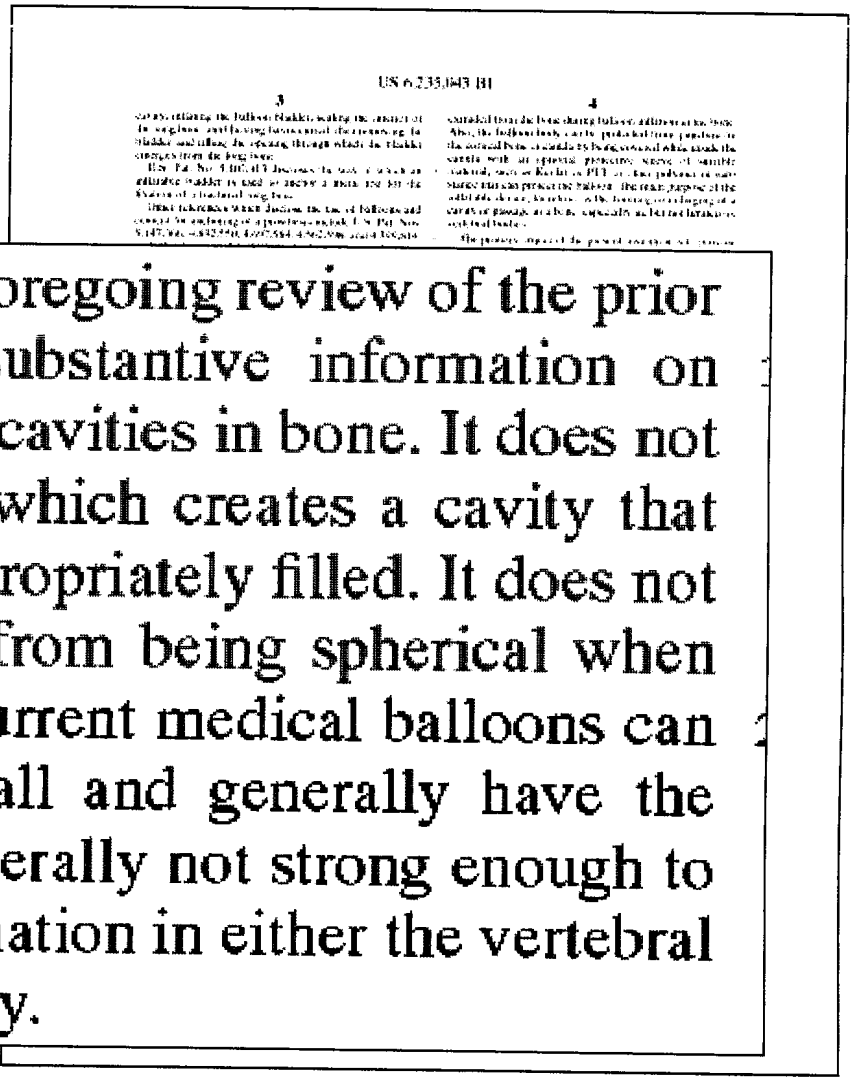


the trabecular bone and/or cancellous bone against the inner surface of the cortical wall of the bone to be treated can be significantly improved with the use of inflatable devices that incorporate additional engineering features not heretofore described and not properly controlled with prior inflatable 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

All Claims of the '043 Patent Require a Balloon

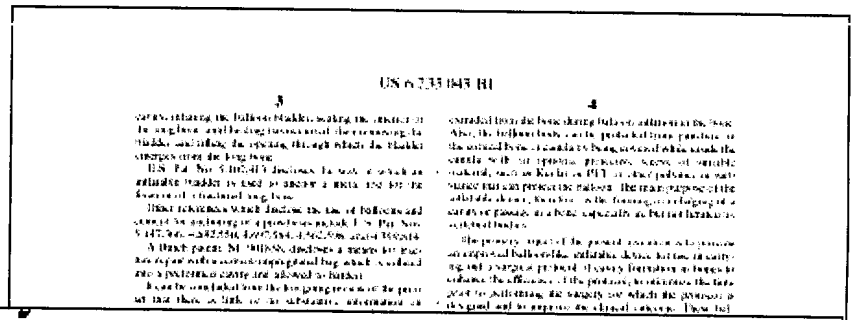
The Background of Invention Distinguishes from the Prior Art:



It can be concluded from the foregoing review of the prior art that there is little or no substantive information on inflatable devices used to create cavities in bone. It does not teach the shape of the balloon which creates a cavity that best supports the bone when appropriately filled. It does not teach how to prevent balloons from being spherical when inflated, when this is desired. Current medical balloons can compress bone but are too small and generally have the wrong configuration and are generally not strong enough to accomplish adequate cavity formation in either the vertebral bodies or long bones of the body.

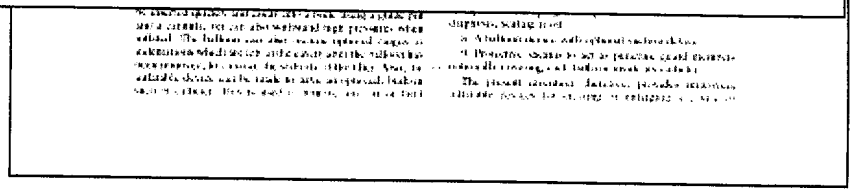
All Claims of the '043 Patent Require a Balloon

The Background of Invention Distinguishes from the Prior Art:



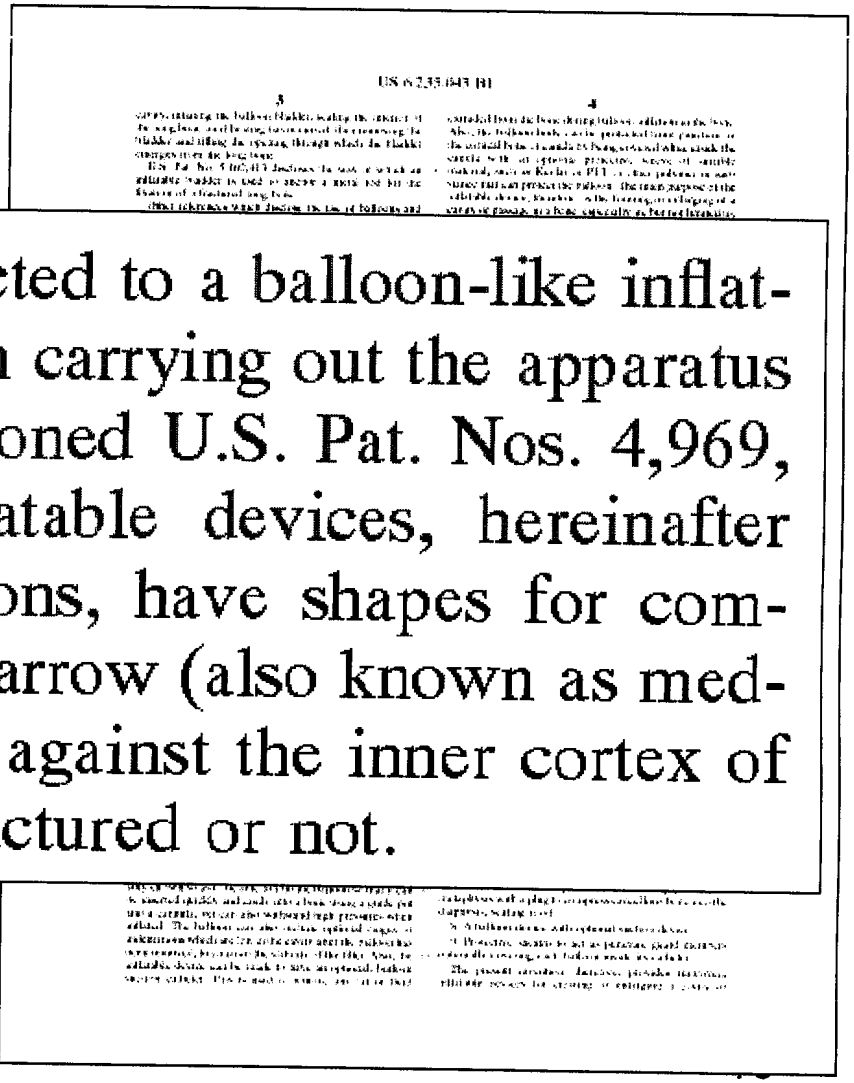
U.S. Pat. Nos. 4,969,888 and 5,108,404 disclose a checker-shaped balloon for compressing cancellous bone, but does not provide information on how this balloon remains in its shape when inflated.

Thus, the need continues for an improved inflatable device for use with pathological bones and the treatment thereof.



All Claims of the '043 Patent Require a Balloon

The Summary of Invention:



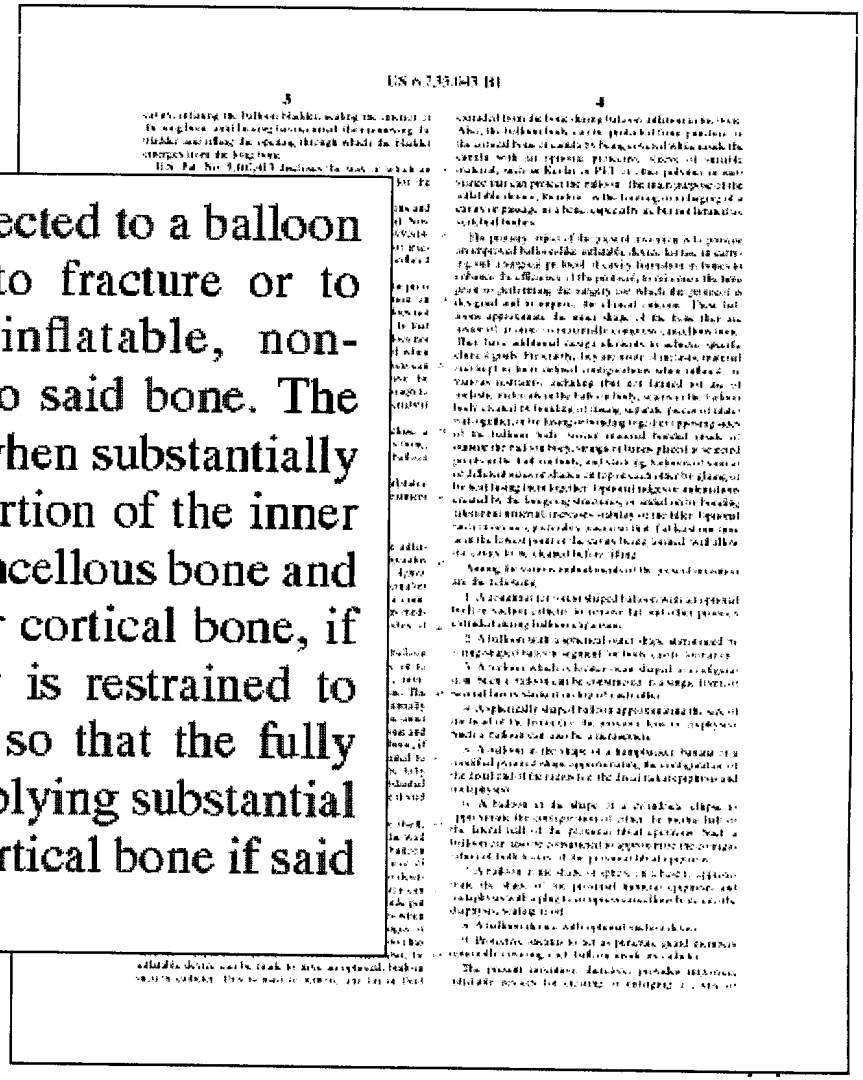
The present invention is directed to a balloon-like inflatable device or balloon for use in carrying out the apparatus and method of the above-mentioned U.S. Pat. Nos. 4,969,888 and 5,108,404. Such inflatable devices, hereinafter sometimes referred to as balloons, have shapes for compressing cancellous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

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All Claims of the '043 Patent Require a Balloon

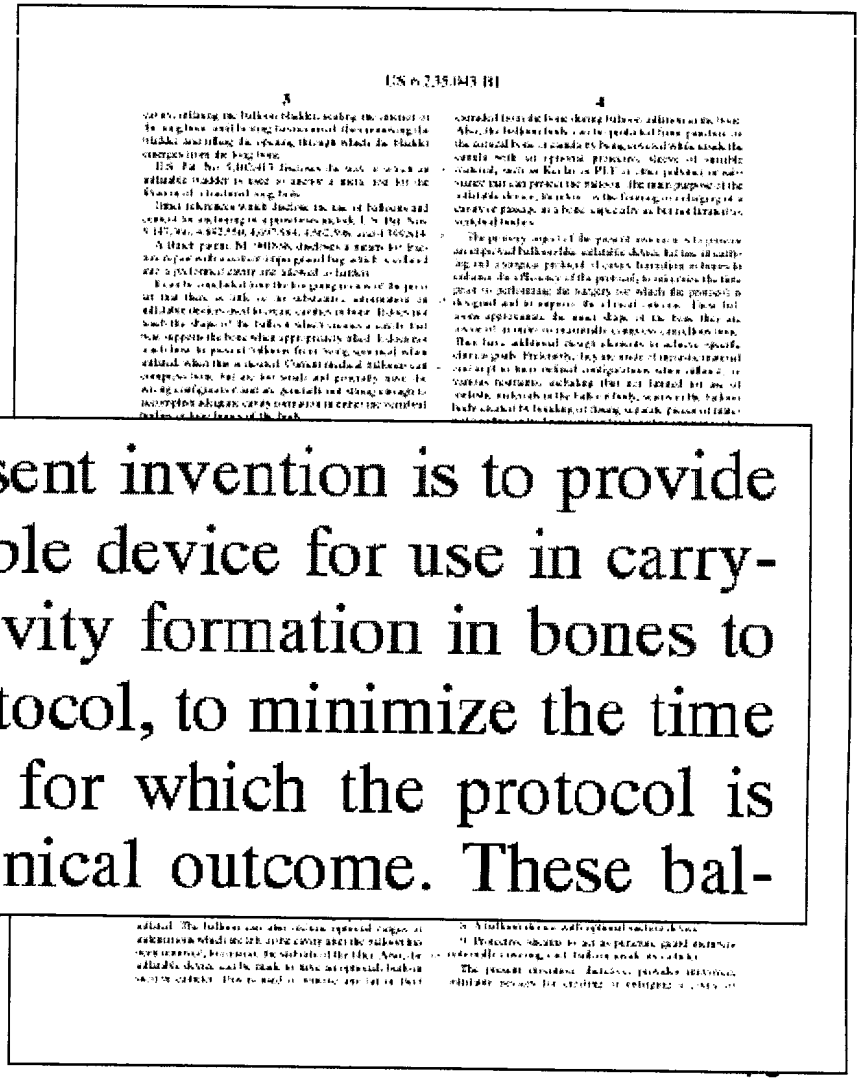
The Summary of Invention:

In particular, the present invention is directed to a balloon for use in treating a bone predisposed to fracture or to collapse. The balloon comprises an inflatable, non-expandable balloon body for insertion into said bone. The body has a predetermined shape and size when substantially inflated sufficient to compress at least a portion of the inner cancellous bone to create a cavity in the cancellous bone and to restore the original position of the outer cortical bone, if fractured or collapsed. The balloon body is restrained to create said predetermined shape and size so that the fully inflated balloon body is prevented from applying substantial pressure to the inner surface of the outer cortical bone if said bone is unfractured or uncollapsed.



All Claims of the '043 Patent Require a Balloon

The Summary of Invention:

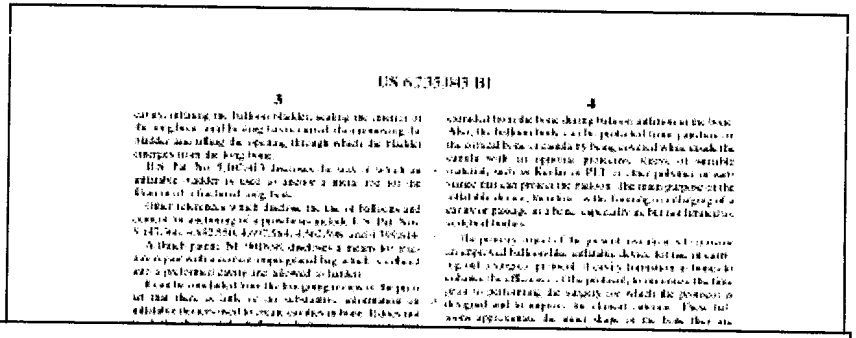


The primary object of the present invention is to provide an improved balloon-like inflatable device for use in carrying out a surgical protocol of cavity formation in bones to enhance the efficiency of the protocol, to minimize the time prior to performing the surgery for which the protocol is designed and to improve the clinical outcome. These bal-

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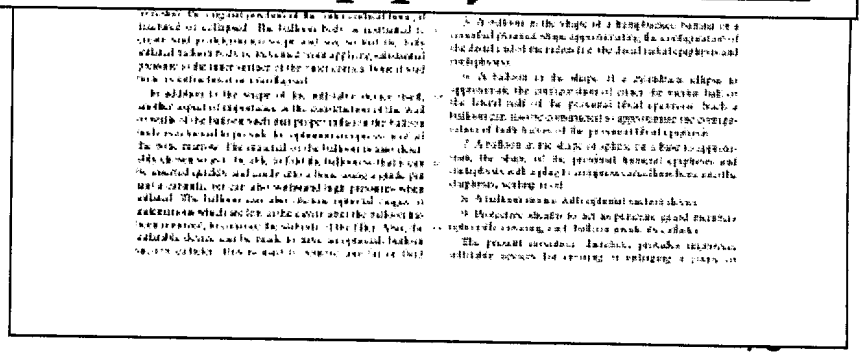
All Claims of the '043 Patent Require a Balloon

The Summary of Invention discloses nine types of balloons:



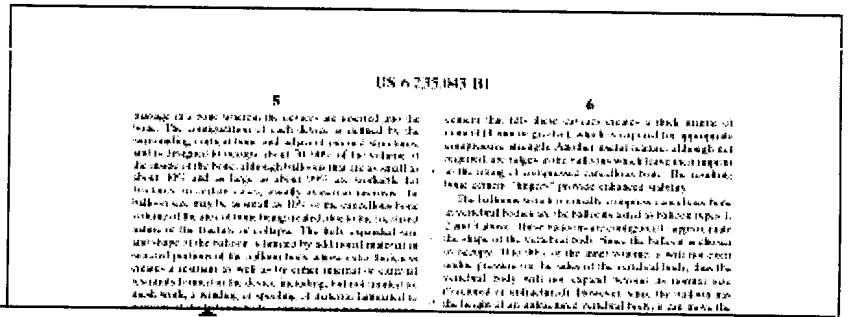
9. Protective sheaths to act as puncture guard members optionally covering each balloon inside its catheter.

metaphysis with a plug to compress cancellous bone into the diaphysis, sealing it off.



All Claims of the '043 Patent Require a Balloon

The Summary of Invention, Stated Goals and Solutions:


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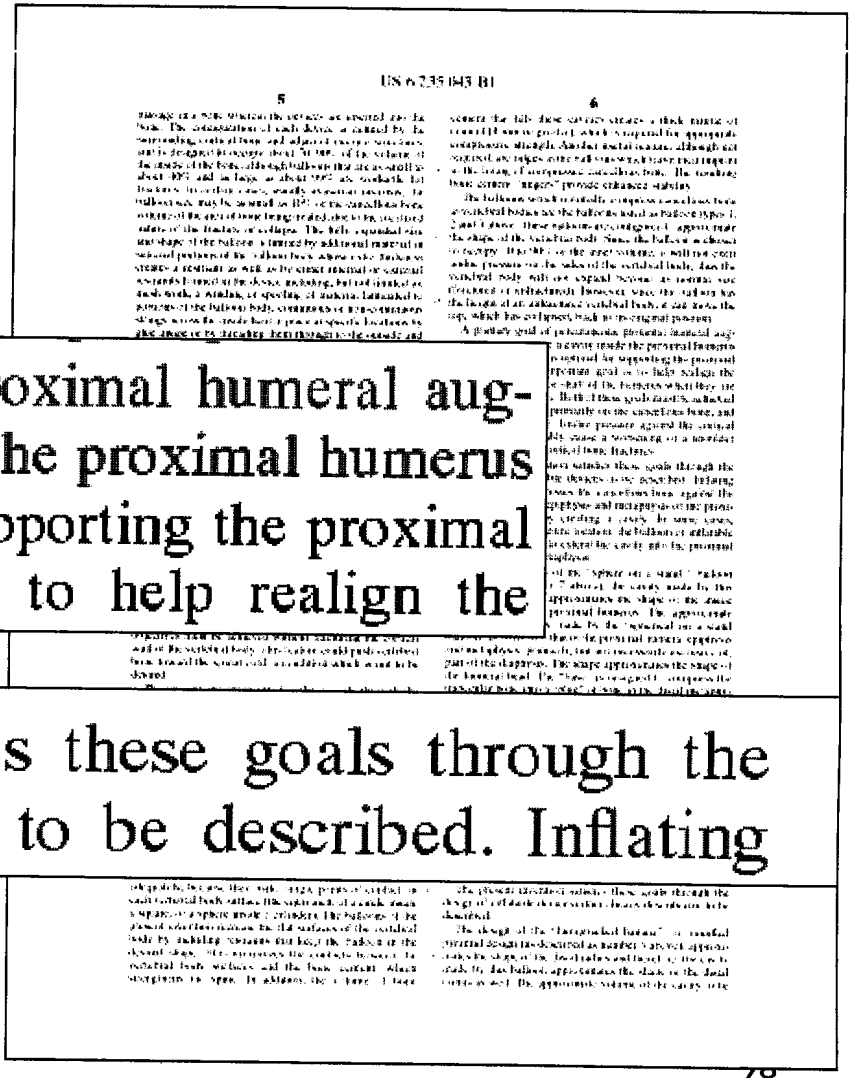
A primary goal of percutaneous vertebral body augmentation of the present invention is to provide a balloon which can create a cavity inside the vertebral body whose configuration is optimal for supporting the bone. Another important

The present invention satisfies these goals through the design of inflatable devices to be described. Inflating such a

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All Claims of the '043 Patent Require a Balloon

The Summary of Invention, Stated Goals and Solutions:



A primary goal of percutaneous proximal humeral augmentation is to create a cavity inside the proximal humerus whose configuration is optimal for supporting the proximal humerus. Another important goal is to help realign the

The present invention satisfies these goals through the design of the inflatable devices to be described. Inflating

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