Claim 2 of the '043 Patent
Internal Restraint Limitation

The Specification teaches the internal restraint:

clinical goals. Preferably, they are made of inelastic material and kept in their defined configurations when inflated, by various restraints, including (but not limited to) use of inelastic materials in the balloon body, seams in the balloon body created by bonding or fusing separate pieces of material together, or by fusing or bonding together opposing sides of the balloon body, woven material bonded inside or outside the balloon body, strings or bands placed at selected points in the balloon body, and stacking balloons of similar or different sizes or shapes on top of each other by gluing or by heat fusing them together. Optional ridges or indentations

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Claim 2 of the '043 Patent
"Constrained Expansion" Limitation

For the reasons already set forth,

"causing constrained expansion of the body"

means:

constraining the expansion of the inflatable body.

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Claim 2 of the '043 Patent
Compacting Element – Requires a Balloon

For the reasons already set forth,

"compacting cancellous bone by the constrained expansion"

means:

using an inflatable body to form a void in the interior of a bone, where the expansion of the inflatable body is restrained by a structure connected to the interior of the inflatable body that limits movement of the internal walls of the inflatable body.

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All Claims of the '043 Patent Require a Balloon

Claim 17, with disputed claim terms in bold:

17. A method for treating bone comprising the steps of inserting inside bone a device comprising a **body adapted to be inserted into bone and undergo expansion** in cancellous bone to compact cancellous bone, **the body including at least two materials that, during the expansion** in cancellous bone, **apply a force capable of moving fractured cortical bone and constrain the expansion** in cancellous bone,

causing constrained expansion of the body in cancellous bone, and

compacting cancellous bone by the constrained expansion.

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CLAIM CONSTRUCTION
Claim 17 of the '043 Patent
DOT's Proposed Construction

- a body adapted to be inserted into bone and undergo expansion → an inflatable body that can be inserted into bone and expanded

- the body including at least two materials that, during the expansion in cancellous bone, apply a force capable of moving fractured cortical bone and constrain the expansion → an inflatable body that can be inserted into bone and expanded, the inflatable body including at least two materials, one of which constrains its expansion by an internal or external structure connected to the inflatable body that limits movement of the walls of the inflatable body.

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CLAIM CONSTRUCTION
Claim 17 – "Two Materials"

- Internal or External Structure Connected to the Inflatable Body That Limits Movement of the Walls of the Inflatable Body

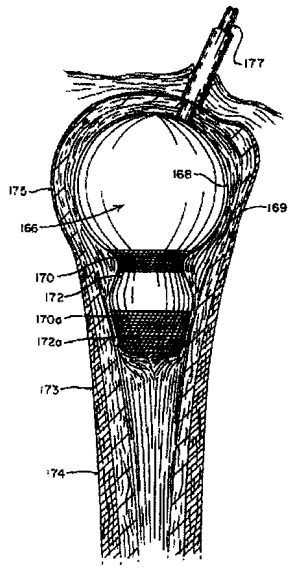


FIG. 18

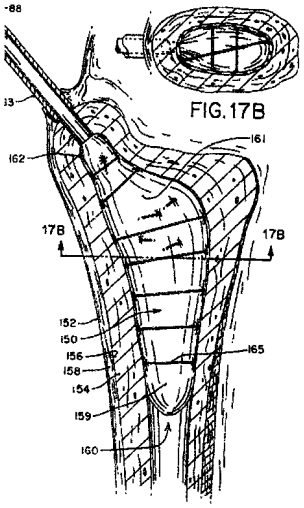


FIG. 17B

FIG. 17A

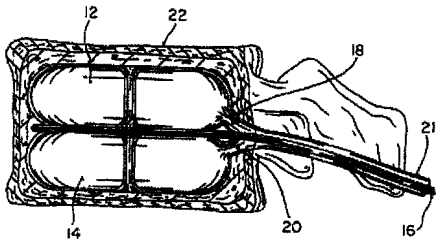


FIG. 2

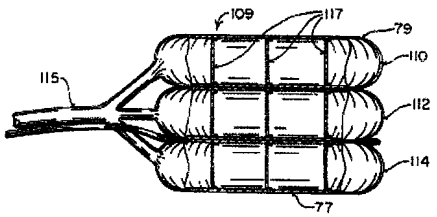


FIG. 3

CLAIM CONSTRUCTION
Claim 17 of the '043 Patent
DOT's Proposed Construction

- causing constrained expansion of the body in cancellous bone → constraining the expansion of the inflatable body

- compacting cancellous bone by the constrained expansion → using an inflatable body to form a void in the interior of a bone, where the expansion of the inflatable body is restrained by a structure connected to the interior of the inflatable body that limits movement of the internal walls of the inflatable body.

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THE SKy DEVICE DOES NOT INFRINGE KYPHON'S BALLOON BONE TAMP PATENTS

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The SKy Device Does Not Infringe the '888 and '404 Patents

- No Literal Infringement
- No Infringement Under the Doctrine of Equivalents

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The SKy Device Does Not Literally Infringe The '888 and '404 Patents

- The SKy Device does not use a balloon
  - The SKy Device uses a rigid polymer tube
- The SKy Device does not use hydraulic expansion
  - The SKy device uses mechanical expansion (folded petals)
- The SKy Device does not compact to create an egg shell void
  - The SKy Device interdigitates with a petal like configuration

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