



Contacts:

Denise Franklin	Jeff Warren
Public Relations	Investor Relations
408-548-5394	763-505-2696

**DESCRIPTION, KEY FINDINGS AND LIMITATIONS**

*Study Comparing Balloon Kyphoplasty to Non-surgical Care in Treating Acute Vertebral Compression Fractures<sup>i</sup>*

**Description**

The study evaluated patients with acute painful vertebral compression fractures resulting from osteoporosis, multiple myeloma or osteolytic metastatic tumors. Eligible patients were randomized to either balloon kyphoplasty (N=149) or a non-surgical control group (N=151). Patients in the control group received therapies such as pain medication, physical therapy, back braces and bed rest. Multiple outcomes relating to quality of life, physical function, mobility and back pain were evaluated at one, three, six and 12 months. The primary outcome was the difference in the change from baseline at one month in the SF-36 physical component summary between the groups. All patients were included in the intent-to-treat analysis of the one-year follow-up results. A total of 235 patients completed follow-up, including (N=124) balloon kyphoplasty patients and (N=111) non-surgical control patients. None of the balloon kyphoplasty patients lost to follow-up withdrew because of a procedure-related adverse event. Two-year follow-up data are being analyzed and will be reported subsequently.

## Key Findings:

- **Better Quality of Life:** Balloon kyphoplasty made it possible for patients to have better quality of life within one month after surgery as compared to the non-surgical control group. They showed greater improvements than the non-surgical group in two quality of life measures. Their SF-36 physical component summary score improved 5.2 points more than the control group at one month ( $p<0.0001$ ), and they maintained an average 3.5 point statistically significant improvement throughout the 12-month follow-up period ( $p=0.0004$ ). Additionally, the EuroQol 5 Domain score for balloon kyphoplasty patients was better by 0.18 points ( $p=0.0003$ ) and 0.12 points ( $p=0.0252$ ) at one and 12 months, respectively, and was statistically significant.
- **Quicker Return of Physical Function:** Balloon kyphoplasty patients showed a 2.5-times greater improvement in performing daily activities one month after surgery than the non-surgical group. Their scores on the 24-point Roland-Morris back function scale showed a statistically significant improvement of 4.0 points more than the non-surgical group at one month ( $p<0.0001$ ) and 2.6 points more at 12 months ( $p=0.0012$ ).
- **Faster Pain Relief:** The level of pain relief reached by balloon kyphoplasty patients one week after surgery was three-times greater than that seen in the non-surgical group. Back pain decreased a statistically significant 2.2 points more in the balloon kyphoplasty patients one week after the procedure ( $p<0.0001$ ). Pain was still down a statistically significant 0.9 points more in the balloon kyphoplasty patients at 12 months ( $p=0.0034$ ). Consistent with this, a significantly smaller percentage of balloon kyphoplasty patients required narcotic analgesics between one and six months ( $p=0.041$ ), required less use of walking aids during follow up, and had an estimated 60 fewer days of limited activity due to back pain over 12 months.

- **Safety** – Balloon kyphoplasty was performed safely with no significant difference in the overall frequency of adverse events or increased risk in incident radiographic vertebral fractures compared to the non-surgical patients. There were also no procedure- or device-related deaths or neurologic, pulmonary or cardiac complications with balloon kyphoplasty. In the balloon kyphoplasty group there were two procedure related serious adverse events (hematoma and urinary tract infection).

### **Limitations**

As with all clinical studies, there are limitations. Patients' responses and radiologists' assessments may have been influenced by the fact the intervention was not blinded. The high, similar incidence of new vertebral fractures in both groups might have decreased the apparent improvements in pain and disability with balloon kyphoplasty. More non-surgical patients discontinued participation, but there were no significant differences between groups in baseline pain, function and quality of life for those who completed the 12 months. Non-surgical treatment was not standardized for each center.

**Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's Annual Report on Form 10-K for the year ended April 25, 2008. Actual results may differ materially from anticipated results.**

Balloon kyphoplasty incorporates technology developed by Gary K. Michelson, M.D.

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<sup>i</sup> Wardlaw W, Cummings SR, Van Meirhaeghe J, et al. Efficacy and safety of balloon kyphoplasty compared with non-surgical care for vertebral compression fracture (FREE): a randomised controlled trial. *Lancet*. 2009; Vol 373. Published on [www.thelancet.com](http://www.thelancet.com) on February 24, 2009.