July 5, 2011

WELLS FARGO SECURITIES

Equity Research

Medtronic, Inc.

MDT: Spine Journal Represents Tip Of Iceberg--Downgrading Shares Downgrading To Market Perform

Market Perform

Sector: Cardiology
Market Weight

Rating Change

EPS	2011A	2012E Curr.	2012E Prior	2013E Curr.	2013E Prior
Q1 (July)	$0.80	$0.80	NC	NE	
Q2 (Oct.)	0.82	**0.82**	**0.84**	NE	
Q3 (Jan.)	0.86	**0.85**	**0.84**	NE	
Q4 (Apr.)	0.90	**0.96**	**0.99**	NE	
FY	$3.37	**$3.43**	**3.47**	**$3.74**	**3.75**
CY	$3.37	$3.66		NE	
FY P/E	11.6x	11.4x		10.5x	
Rev.(MM)	$15,932	$16,491		$17,045	

Source: Company Data, Wells Fargo Securities, LLC estimates, and Reuters
NA = Not Available, NC = No Change, NE = No Estimate, NM = Not Meaningful
V = Volatile, = Company is on the Priority Stock List

- **Summary:** We believe the InFuse papers published in The Spine Journal on June 28 will have broader implications for MDT and its spine business than the Street currently expects. We think The Spine Journal papers could lead to the following outcomes: (1) a significant reduction in the sales of MDT's spine biologics franchise; (2) a reduction in the sales of MDT's spinal instrumentation business; (3) a potential FDA review of InFuse, including an Advisory Committee meeting, which could lead to more limited use of InFuse; (4) potentially larger criminal penalties in the Department of Justice (DOJ) investigation of the off-label promotion of InFuse; (5) the potential emergence of class action lawsuits; and (6) the potential sale of the entire spine business. While we previously expected MDT's spine biologics franchise to decline by 9% in FY2012 due to the non-approvable letter for Amplify (higher dose version of InFuse) and a likely DOJ settlement for off-label promotion of InFuse in CY2011, the attack of InFuse by The Spine Journal and the accompanying negative media coverage was unexpected. Given the increasing negative publicity for InFuse and the likely negative spillover to MDT's larger spinal instrumentation business, we are reducing our FY2012E-13E sales by $209MM and $322MM, respectively, to $16.491B and $17.045B. In addition, we are lowering our FY2012E-13E EPS by $0.04 and $0.01, respectively, to $3.43 and $3.74. Our new FY2012E EPS is at the low end of MDT's FY2012 guidance range. We are lowering our valuation range to $36-37 from $46-47 which assumes 10x our new CY2012 EPS estimate.

- **Background On The Spine Journal Papers.** On June 28, The Spine Journal, which is the official journal of the North American Spine Society (NASS), published an entire issue dedicated to InFuse. The publication included a review article on the 13 original industry-sponsored studies of InFuse which concluded that the study authors downplayed the adverse events with InFuse. In addition, many of the study authors received significant amounts of money from MDT. The review article found 4 main areas of concern: (1) conflicts of interest were not reported or were unclear; (2) the study designs were biased in favor of InFuse; (3) the studies included invalid claims associated with the control groups; and (4) common and serious complications with InFuse were not reported. The authors of the review article indicated that the authors of the original InFuse studies were indirectly paid $12-16MM per study. MDT issued a statement in which it acknowledged the questions raised by The Spine Journal regarding the conclusions by the study authors in the original InFuse publications, however, MDT believes that it has properly submitted data to FDA and included the InFuse complications in the InFuse product label.

Ticker	MDT
Price (07/01/2011)	$39.12
52-Week Range:	$30-44
Shares Outstanding: (MM)	1,084.0
Market Cap.: (MM)	$42,406.1
S&P 500:	1,339.67
Avg. Daily Vol.:	6,252,980
Dividend/Yield:	$0.44/1.1%
LT Debt: (MM)	$5,802.0
LT Debt/Total Cap.:	39.0%
ROE:	20.0%
3-5 Yr. Est. Growth Rate:	14.0%
CY 2011 Est. P/E-to-Growth:	0.8x
Last Reporting Date:	05/24/2011 Before Open

Source: Company Data, Wells Fargo Securities, LLC estimates, and Reuters

Valuation Range: $36.00 to $37.00 from $46.00 to $47.00
Our 12-month valuation of $36-37 assumes 10x our CY2012E EPS. Key risks include ICD and spine market growth and additional share losses.

Investment Thesis:
We believe issues with MDT's InFuse will negatively impact its spine business and the DOJ investigation of ICDs will negatively impact the ICD market.

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Please see page 6 for rating definitions, important disclosures and required analyst certifications

Company Description:

Founded in 1949, Minneapolis-based Medtronic (MDT) is a leading global medical technology company focused on providing therapies for chronic disease. The company has eight operating segments: cardiac rhythm disease management (CRDM), spinal and navigation, vascular, neurological, diabetes, cardiac surgery, ear, nose, and throat (ENT) and physio-control. Revenue for MDT's FY2009 (ended April 27, 2009) totaled $14.6B, up 8% year over year. Medtronic is the leader in CRDM with sales of $5.0B in FY2009.

Discussion:

The Spine Journal Papers Will Result In A Faster And Steeper Decline In InFuse Sales Than We Expected. We believe The Spine Journal papers will reduce InFuse sales by 30-50% in F2012 because (1) hospitals will push back on InFuse use because of liability concerns; (2) payers are not going to want to pay for InFuse; (3) patients will refuse to be treated with InFuse; and (4) some spine surgeons will feel betrayed because the evidence provided to them was not complete. According to MDT, worldwide InFuse sales were $750MM in F2011 or 85% of its spine biologics franchise. InFuse sales had already started declining in F2011 due to safety concerns and we had previously estimated that InFuse sales would decline 17% in F2012 due to the recent non-approvable letter for Amplify (a higher dose version of InFuse) and the likely DOJ settlement for the off-label promotion of InFuse sometime in CY2011. We now estimate that InFuse will decline 40% in F2012 with a portion of the lost InFuse sales being captured by MDT's demineralized bone matrix (DBM) products (see Figure 3 for our current and prior Biologics estimates). We are reducing our overall MDT Biologics sales estimate by $108MM to $698MM in F2012 which assumes -21% YoY growth and we are reducing our F2013 Biologics sales estimate by $183MM to $603MM which assumes -14% YoY growth. Because InFuse has a gross margin of only 55% due to the royalty MDT pays Pfizer, we estimate that InFuse has an operating margin that is slightly below MDT's corporate average of 32%. Although InFuse's gross margin is well below the corporate average of 75%, the marketing costs associated with InFuse are limited because MDT laid off its biologics sales force in CY2010.

We Expect The InFuse Issues To Negatively Impact MDT's Spinal Instrumentation Business. Since MDT laid off the InFuse sales representatives in CY2010, the spinal instrumentation reps have been promoting both InFuse and MDT's spinal instrumentation products. We believe the instrumentation reps have lost some credibility with surgeons due to The Spine Journal papers. In addition, we think spine surgeons will use other bone growth products in their fusion procedures and this will also lead to greater usage of competitor's spinal instrumentation products because the rep is typically in the operating room with the surgeon. We estimate The Spine Journal papers will reduce MDT's spinal instrumentation sales by $101MM in F2012 and $139MM in F2013 versus our previous estimates (see Figure 3). These are relatively high margin products.

We See About A 25% Chance InFuse Is Pulled From The Market. In light of The Spine Journal papers, we think it's likely that FDA will announce a formal review of InFuse. If FDA decides to convene an advisory committee to re-examine InFuse, we think MDT may proactively remove the product from the market. At this time, we handicap the likelihood of MDT pulling InFuse from the market at about 25%. The new CEO, Omar Ishrak, who assumed his position at MDT on June 13, could decide to act swiftly and remove the product if he believes that InFuse will be a lingering distraction for MDT. Mr. Ishrak has requested an internal review of InFuse to be completed in 90 days. We think MDT is more likely to leave InFuse on the market because pulling it may be viewed as admitting wrongdoing. After lowering our InFuse estimates to $448MM in F2012, the product will account for only 2.7% of total MDT sales and EPS. Therefore, if MDT decides to pull InFuse from the market, we would see about 2-3% downside risk to our current estimates. Importantly, The Spine Journal does not recommend that InFuse is removed from the market. In fact, it states that rhBMP-2 (InFuse) still may be of great benefit to a ***small*** (emphasis added by us) group of patients who have serious problems in healing bone.

DoJ Investigation Of InFuse Off-label Promotion Should Heat Up. On October 6, 2008, MDT received a subpoena from the DOJ looking into the off-label promotion of InFuse. Our legal consultant believes that a settlement could occur sometime in 2011. The DOJ could pursue damages on both civil and criminal grounds. Our consultant believes that the civil damages are likely to be limited because the damages are measured based on the sales for procedures and patients that are federal healthcare beneficiaries. Therefore, the incremental cost to the government for off-label use of InFuse is modest because (1) Medicare patients make up a small percent of spinal fusion patients and (2) InFuse is reimbursed as part of the spinal fusion DRG, therefore, using InFuse in a procedure does not cost the government more money. On the criminal side, the promotion damages are measured based on sales to the government and private payers. Our consultant believes that the criminal damages are likely to be larger than the civil damages. We believe that The Spine Journal papers could lead to greater criminal damages if a direct connection can be made between MDT and the complications reported by the authors of the original MDT-sponsored InFuse papers. For example, an

article in the Wall Street Journal on June 28 included a quote from an email from one of the authors of an early InFuse paper seeking input from MDT on the manuscript. At this time, it is impossible for us to estimate how much MDT will have to pay to settle the investigation into the off-label promotion of InFuse. However, we do believe this will generate some negative publicity for MDT.

Class Action Lawsuits May Emerge – Uncertainty Over Final Settlement Could Create An Overhang. We expect plaintiff's attorneys to attempt to show that InFuse was used widely because of off-label promotion (see DOJ investigation above). We also expect plaintiff's attorneys to attempt to link MDT to the under-reporting of adverse events in the medical literature by highlighting that The Spine Journal papers were company-sponsored studies and the authors were loyal to the company. The attorneys will likely allege that the surgeons who wrote the papers were paid by MDT and were incentivized to not report all complications. Importantly, the under-reporting of complications in the medical literature could raise questions regarding the process of reporting post-marketing complications by MDT. In previous situations like this it has not been difficult for plaintiff's attorneys to use internal company documents to make drug and device manufacturers appear negligent in our view.

Precedents Imply A Broad Range Of Liability Costs. We estimate that about 934,000 patients in the U.S. have undergone spinal fusion surgery with InFuse (see Figure 1). Using data from 5 recent high profile class action drug and device settlements, we estimate the cost to MDT to settle the likely InFuse class action law suits will range from $70MM to $8B with the median being $1.2B (see Figure 2). Because InFuse is regulated as device, it will be protected to some degree from pre-emption which limits product liability for devices. The key metric to watch going forward in our view will be the number of claims. For reference, there were about 208,000 patients who received MDT's Fidelis ICD lead and MDT settled all claims in the U.S. for $268MM or $33,000 per claim. If we assume a similar percent of claims with InFuse, the amount to settle InFuse claims in the U.S. will be about $1.2B. We would view a settlement cost of $1.2B as manageable for MDT because the lost interest income on $1.2B would be only about $24MM per year assuming 2% interest.

Figure 1: Estimated Number Of Cumulative InFuse Patients In The U.S.

	F2003 A	F2004 A	F2005 A	F2006 A	F2007 A	F2008A	F2009 A	F2010 A	F2011 A
Spinal Biologics Sales ($MMM)	77	258	413	572	697	815	839	867	884
InFuse Worldwide Sales ($MM)	70	234	375	519	633	740	762	787	750
InFuse US Sales ($MM)	65	218	349	484	590	689	710	733	699
InFuse US Patients ('000)	13	45	72	100	121	142	146	151	144
Cumulative InFuse US Patients ('000)									934

Source: Company reports, Wells Fargo Securities, LLC estimates

Figure 2: Estimated Product Liability Cost To MDT For InFuse Class Action Lawsuits

Litigation	Company	Est. U.S. Patients ('000)	Total Claims	% of Patients Filing Claim	Settlement Cost ($MM)	Settlement Cost Per Claim ($)	Settlement Cost per Patient ($)
Fen-Phen	Wyeth	6,500	573,433	8.8%	21,000	36,622	3,231
Vioxx	Merck	20,000	50,000	0.3%	4,850	97,000	243
Marquis/Maximo/InSync	MDT	77	2,682	3.5%	114	42,506	1,489
Guidant ICD	BSX	288	8,550	3.0%	240	28,070	833
Fidelis	MDT	208	8,100	3.9%	268	33,086	1,288
InFuse Est.	MDT	934	--	--	–	--	--
High	MDT	934	82,375	8.8%	7,990	97,000	3,231
Median	**MDT**	**934**	**32,710**	**3.5%**	**1,198**	**36,622**	**1,288**
Low	MDT	934	2,334	0.3%	66	28,070	243

Source: Company reports, New York Times, Wall Street Journal, Diet Drug Settlement website, Wells Fargo Securities, LLC estimates

InFuse Issues Could Lead To MDT Ultimately Divesting Its Spine Business. We think the issues with InFuse could be the trigger for the MDT board to consider selling the spine business. The spine business has been a challenging area for MDT over the past few years and the issues with InFuse will likely make the next few years tough as well for this business. Depending on the price, we think investors would generally welcome the decision to divest the spine business. MDT's spine business accounted for 21% of total MDT sales in F2011.

Competition Should Benefit From InFuse Issues But Overall Procedure Volume Could Be Softer. We understand that NUVA's Osteocel and OFIX's Trinity are competing head-to-head with InFuse and that these products are taking share partly due to their lower cost. Osteocel and Trinity are allograft cellular bone matrix products. We believe that sales of these two products were about $120MM in 2010. We

have also heard that BAX's Actifuse is also growing at InFuse's expense. We would expect these three products to be the largest beneficiaries of the InFuse issues. On the spinal hardware side, competitors such as JNJ, NUVA, and SYK could benefit from any lost MDT hardware sales, however, this may be offset if the negative InFuse publicity has a negative spillover effect on overall spine procedures.

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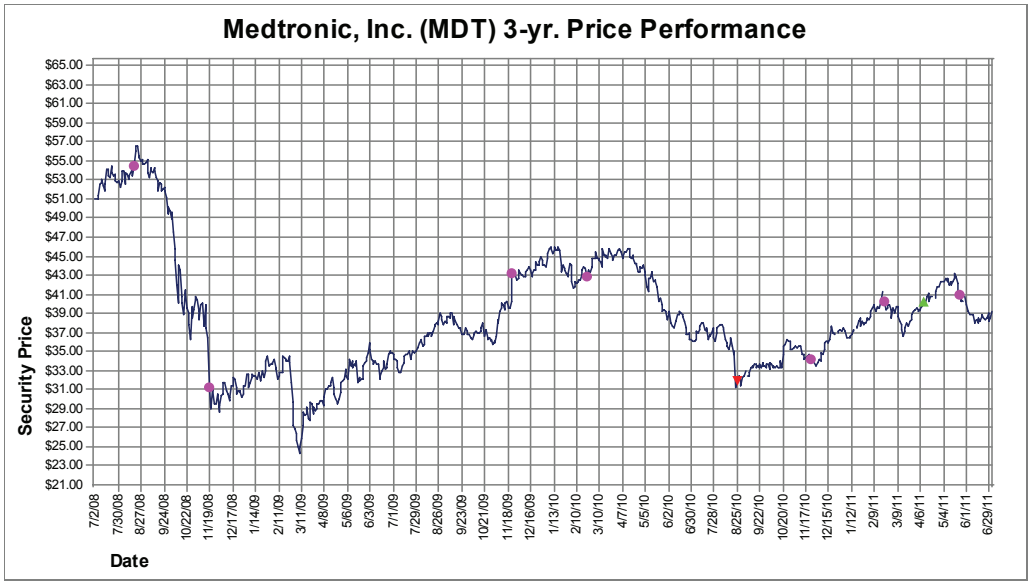
Figure 3: Our Prior And Current MDT Spine Sales Estimates

	F2011 A	F2012 E	F2013 E	F2014 E	F2015 E
Prior Estimates ($MM)					
Biologics	884	806	786	781	780
InFuse	750	626	606	601	600
Other	134	180	180	180	180
Instrumentation	2,116	2,166	2,240	2,321	2,411
Kyphon	414	394	381	381	381
TOTAL	3,414	3,366	3,407	3,483	3,572
Year-over-Year Growth (%)					
Biologics	2.0%	-8.9%	-2.5%	-0.6%	-0.2%
Infuse	-4.7%	-16.5%	-3.2%	-0.7%	-0.2%
Other	67.5%	34.3%	0.0%	0.0%	0.0%
Instrumentation	-2.2%	2.4%	3.4%	3.6%	3.9%
Kyphon	-11.7%	-4.8%	-3.2%	-0.2%	0.1%
TOTAL	-2.4%	-1.4%	1.2%	2.2%	2.5%
Current Estimates ($MM)					
Biologics	884	698	603	549	500
Infuse	750	448	353	299	250
Other	134	250	250	250	250
Instrumentation	2,116	2,065	2,101	2,138	2,178
Kyphon	414	394	381	381	381
TOTAL	3,414	3,157	3,085	3,068	3,059
Year-over-Year Growth (%)					
Biologics	2.0%	-21.1%	-13.6%	-9.0%	-8.9%
Infuse	-4.7%	-40.3%	-21.3%	-15.3%	-16.3%
Other	67.5%	86.6%	0.0%	0.0%	0.0%
Instrumentation	-2.2%	-2.4%	1.7%	1.8%	1.8%
Kyphon	-11.7%	-4.8%	-3.2%	-0.2%	0.1%
TOTAL	-2.4%	-7.5%	-2.3%	-0.6%	-0.3%
Difference (Current vs Prior Estimates)					
Biologics	--	(108)	(183)	(233)	(280)
Infuse	--	(178)	(253)	(303)	(350)
Other	--	70	70	70	70
Instrumentation	--	(101)	(139)	(183)	(233)
Kyphon	--	0	0	0	0
TOTAL	--	(209)	(322)	(416)	(513)
% Change		-1.3%	-1.9%	-2.3%	-2.7%
EPS Impact*					
Sales Impact ($MM)		(209)	(322)	(416)	(513)
Operating Income ($MM)		(63)	(97)	(125)	(154)
Net Income ($MM)		(44)	(68)	(87)	(108)
EPS Impact ($)		(0.04)	(0.06)	(0.08)	(0.10)
% of Total EPS		-1.2%	-1.7%	-2.1%	-2.4%

* actual EPS impact expected to be mitigated by cost reductions

Source: Company reports, Wells Fargo Securities, LLC estimates

Required Disclosures



	Date	Publication Price ($)	Rating Code	Val. Rng. Low	Val. Rng. High	Close Price ($)
	7/2/2008		Biegelsen			
	7/2/2008	NA	1	57.00	59.00	50.94
●	8/19/2008	54.48	1	61.00	63.00	54.48
●	11/19/2008	31.60	1	40.00	42.00	31.20
●	11/24/2009	43.25	1	46.00	48.00	43.25
●	2/23/2010	42.87	1	49.00	51.00	42.87
▼●	8/25/2010	31.21	2	32.00	33.00	31.87
●	11/23/2010	34.18	2	36.00	37.00	34.18
●	2/22/2011	40.21	2	40.00	42.00	40.21
▲●	4/11/2011	39.67	1	47.00	48.00	40.24
●	5/24/2011	40.42	1	46.00	47.00	40.88

Source: Wells Fargo Securities, LLC estimates and Reuters data

Symbol Key

- ▼ Rating Downgrade
- ▲ Rating Upgrade
- ● Valuation Range Change
- ◆ Initiation, Resumption, Drop or Suspend
- ■ Analyst Change
- ❒ Split Adjustment

Rating Code Key

1	Outperform/Buy	SR	Suspended
2	Market Perform/Hold	NR	Not Rated
3	Underperform/Sell	NE	No Estimate

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MDT: Key risks include ICD and spine market growth and additional share losses.

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O=Overweight: Industry expected to outperform the relevant broad market benchmark over the next 12 months.
M=Market Weight: Industry expected to perform in-line with the relevant broad market benchmark over the next 12 months.
U=Underweight: Industry expected to underperform the relevant broad market benchmark over the next 12 months.

VOLATILITY RATING

V = A stock is defined as volatile if the stock price has fluctuated by +/-20% or greater in at least 8 of the past 24 months or if the analyst expects significant volatility. All IPO stocks are automatically rated volatile within the first 24 months of trading.

As of: July 5, 2011

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