

Web MSNBC

Search

Alerts | Newsletters | RSS | Help | MSN Home | Hotmail | Sign In



MSNBC Home Health Heart Health

Sponsored by

advertisement Shopping on MSN



Great gift ideas

- For everyone
- For him
- For her

Guidant recalls thousands of pacemakers

170,000 top-selling implanted heart devices could fail, company warns

Associated Press
Updated: 5:01 p.m. CT Sept 22, 2005

INDIANAPOLIS - Guidant Corp. issued recalls or safety advisories for almost 170,000 of its top-selling pacemakers on Thursday following a two-week federal inspection of its cardiac unit.

Since June, Indianapolis-based Guidant has recalled or issued warnings about 88,000 heart defibrillators — including its leading seller, the Contak Renewal 3 — and almost 200,000 pacemakers because of reported malfunctions. Pacemakers use mild electrical current to speed a slow heartbeat; defibrillators use a bigger jolt to correct life-threatening irregular heartbeats. Surgery to remove and replace the devices is risky.

The latest advisory is the fifth in three months by the nation's second-largest cardiac-device maker and has renewed questions over its reporting of potential problems and a planned \$25.4 billion acquisition by New Jersey-based Johnson & Johnson. Some 80 percent of Guidant's heart products are now under recall or an advisory, according to an estimate by Jan Wald, an analyst with A.G. Edwards & Sons.

"It's gotten so that we keep waiting for the other shoe to drop," said Dr. Douglas Zipes, a heart expert at the Indiana University School of Medicine.

Johnson & Johnson stands by its August statement that it continues to work with Guidant on the impact of the recall announcements, spokesman Jeffrey Leebaw said. The company expects a decision on the merger by the Federal Trade Commission in October.

Insignia and Nexus lines

Guidant's announcement Thursday, which focused on its top-selling Insignia and Nexus lines, affects about 56 percent of the company's pacemakers. The company urged patients to consult with their doctor but did not say the devices should be removed.

Failures in the devices has led to nine cases of emergency hospitalization, but no deaths, Guidant said.

A Food and Drug Administration report found that failures with the Insignia line were first reported in 2003 and occurred as recently as July. As of September, users had not been informed of the potential for failure and the company continued to distribute the product, the report said.

CLICK FOR RELATED CONTENT

MOST POPULAR

Most Viewed • Top Rated • Most E-mailed

- Will Antarctica be changed by big cruise ship?
- 9/11 conspiracy theorists multiply
- Lohan's Hermes handbag stolen at Heathrow
- Footage shows bin Laden with 9/11 hijackers
- Panda inconsolable after crushing cub
- **Most viewed on MSNBC.com**

MEDPAGE TODAY

Implantable Devices Take a Licking but Don't Always Keep on Ticking

It would seem reasonable that if an implantable cardioverter-defibrillator or pacemaker develops a flaw, the patient should be among the first to know.



Physicians... Earn CME with your medical news

Health

- Diet & Nutrition
- Fitness
- Women's Health
- Children's Health
- Men's Health
- Sexual Health
- Low Blow
- Aging
- Cancer
- Heart Health
- Mental Health
- More Health News
- Pet Health
- Health Library
- Health Columns

Video

U.S. News

Politics

World News

Business

Sports

Entertainment

Health

Tech / Science

Weather

Travel

Blogs Etc.

Local News

Newsweek

Multimedia

Most Popular

NBC NEWS

MSNBC TV

Today Show

Nightly News

Meet the Press

Dateline NBC

• Disable Fly-out

Shopping

Dating

Real Estate

Jobs

Autos

Advertisement

MSN SHOPPING



FDA knew of Guidant heart device failures

Guidant said that, as of Sept. 6, it had confirmed loss of pacing output in 36 of 49,500 Insignia and Nexus pacemakers, including seven that were detected by doctors before being implanted. The failures affected devices shipped before March 2004, before a supplier made changes in a timing component, Guidant said.

The company reported telemetry failures in 16 of 341,000 of the pacemakers as well.

Fred McCoy, president of Guidant's Cardiac Rhythm Management division, said the failures were reported in annual filings to the FDA. But he said the issue of when to disclose problems in products is a vexing one.

"One of the problems that any company that deals in high-tech medical technology is dealing with the low likelihood of failure," McCoy said. "The decision about when to communicate actively is something we all struggle with."

Guidant under fire for delays

Guidant has been under fire for waiting years to warn patients about a problem in its Prizm 2 DR defibrillator. Industry officials gathered in Washington last week to discuss standards for notifying the public about issues with the implanted devices, and at least one lawmaker has called for more investigation of Guidant's problems.

"Companies should not be allowed to hide problems until the FDA comes to seek them out," said Rep. Edward J. Markey, D-Mass. "It is not the prerogative of the company to decide whether the defect warrants action — that decision should be left in the hands of the patient with the help of well-informed physicians."

Guidant also said Thursday that it had notified doctors that the failure rate for two defibrillators — the Contak Renewal and Contak Renewal 2 — was nearly triple what it had earlier estimated. The company said the devices, which were recalled June 17, had been associated with three deaths, an increase from one death reported earlier.

Guidant projected a failure rate for the defibrillators of 0.7 percent to 1.8 percent.

Despite the problems, Zipes said pacemakers and defibrillators have provided much-needed treatment to patients with heart problems.

"There's no question that the benefits outweigh the risk," he said.

Guidant spokesman Dave Knutson said the FDA inspection ended Sept. 1 at Guidant's Cardiac Rhythm Management facilities in St. Paul, Minn.

The FDA classified Thursday's recall as Class II, meaning that any injury caused by a malfunction should be temporary or pose a slight threat of a serious nature.

Shares of Guidant rose 86 cents to close at \$70.35 in trading on the New York Stock Exchange. Shares of Johnson & Johnson fell 2 cents to close at \$64.68.

© 2006 The Associated Press. All rights reserved. This material may not be published, broadcast, rewritten or redistributed.

Rate this story **Low** **High**
 Current rating: **4** by **42** users • **View Top Rated stories**

Print this | Email this | IM this

MORE FROM HEART HEALTH

[Next →](#)

Heart Health Section Front

- Company gets OK to sell 4,000 artificial hearts
- 3-in-1 heart pill could save millions
- Cheaper blood thinner just as effective
- Exercise OK for hypertension patients
- Cholesterol drugs cut risk of second stroke
- Safety concerns raised on defibrillators
- Blood pressure surges in stressed workers
- Blood clots outstretch rubber bands
- Test may be able to tell if CPR is futile
- Breathe deep to lower blood pressure
- Heart Health Section Front

Add **Heart Health** headlines to your news reader:



• [More RSS feeds from MSNBC.com](#)

- WP: 9/11 conspiracy theories
- Bin Laden tape marks 9/11 anniversary
- Deadly blast near U.S. embassy in Kabul
- Bush plans prime-time 9/11 speech
- NASA fuels up shuttle for launch advertisement
- Full coverage: Battleground America
- Video: Paris Hilton arrested for DUI
- Vote: Will Paris get special treatment?
- Video: Suri's splashy debut
- Blog: Sharpton endorses Tucker on 'Dancing'

SPONSORED LINKS

Lower Blood Pressure

Resperate relaxes blood vessels to reduce pressure. No side effects.
www.resperate.com

Oprah Has Spoken

"You're going to want to take this test" - the free RealAge test!
www.realage.com

Diet and Exercise - Guaranteed Results

Shop OpAmerica for diet and exercise products that work. Your satisfaction is guaranteed! Find great prices on the diet and exercise products that make it fun and easy to achieve your goals.
www.opamerica.com

The Prostate Formula

Up to 90% of all men will develop an enlarged prostate during their lives, some as early as age 40. Don't worry about your prostate health - do something about it! Find out how.
www.prostateformula.com

Become a Health Counselor

Successful 1 year certification program. Request catalog, start today.
www.integrativenutrition.com

[Cover](#) | [U.S. News](#) | [Politics](#) | [World News](#) | [Business](#) | [Sports](#) | [Tech/Science](#) | [Entertainment](#) | [Travel](#) | [Health](#) | [Blogs Etc.](#) | [Weather](#) | [Local News](#)
[Newsweek](#) | [Today Show](#) | [Nightly News](#) | [Dateline NBC](#) | [Meet the Press](#) | [MSNBC TV](#)

[About MSNBC.com](#) | [Newsletters](#) | [RSS](#) | [Podcasts](#) | [Help](#) | [News Tools](#) | [Jobs at MSNBC.com](#) | [Contact Us](#) | [Terms & Conditions](#) | [Privacy](#)

© 2006 MSNBC.com