Patient Safety Alert

Veterans Health Administration Warning System
Published by VA Central Office

AL08-07 January 25, 2008

Item: Implant orientation of Implantable Cardioverter Defibrillators (ICDs) and Cardiac Resynchronization Therapy Devices (CRT-Ds) manufactured by Boston Scientific Corporation's Cardiac Rhythm Management Division, previously under the name Guidant.

Specific Incident: A subset of the following Guidant ICDs and CRT-Ds models implanted in a specific location and in an uncommon orientation - beneath the pectoral muscle with the serial number facing the ribs - may be subject to component damage and device malfunction. This can impact the device's ability to deliver appropriate shock therapy.

May 12, 2006 Population

Device Model Name	Model Numbers
Contak Renewal 3 & 3 HE	H170/H173/H175/H177/H179
Contak Renewal 3 AVT & 3 AVT HE	M150/M155/M157/M159
Contak Renewal 4 & 4 HE	H190/H195/H197/H199
Contak Renewal 4 AVT & 4 AVT HE	M170/M175/M177/M179
Vitality DR HE	T180

January 4, 2008 Population

Device Model Name	Model Numbers
Vitality 2 EL DR/VR	T167/T177
Vitality EL	T127
Vitality DR+	1872

Actions:

1. By Close of Business (COB) April 30, 2008, electrophysiology and/or cardiology staff or other appropriate caregivers must identify all affected patients by implementing steps a, b, c and step d if indicated. It is important that ALL INFORMATION sources be reviewed to insure that patients will not be missed, as they may be found on one list and not on another.

   a) Retrieve and review a list of your patients with the affected devices (ICDs) on the VA National ICD Surveillance Center intranet website (https://icdpm.sanfrancisco.med.va.gov, see Attachment 3 for instructions. This list includes all the patients in Guidant's database that have implanted devices affected by this and previous recalls (some devices are affected by more than one recall).

   b) Review your patient records for all patients with implanted Guidant devices affected by this recall.

   c) Review implant surgical notes and post implant Chest X-rays (CXRs) of patients with affected devices identified in steps a and b above, to

determine if device's location and orientation are verifiable. If device location or orientation is not verifiable or a post-implant CXR is not available then proceed to step d.

If device orientation is verified as beneath the pectoral muscle with the serial number facing the ribs then proceed to Action 2 below.

d) Contact the patients identified at step c above (those with device orientation or location not verifiable) to have an Anterior/Posterior (AP) Chest x-ray to determine/verify specific device orientation or to have a physical examination of the implant area to best determine the location of the device.

2. Review and plan appropriate action as discussed in Attachment 2 prepared by Dr. Edmund Keung, Director of the VA National ICD Surveillance Center.

Source: Boston Scientific Corporation (BSCI)

Contacts: BSCI/Guidant (800) 227- 3422.

Dr. Edmund Keung at the VA National ICD Surveillance Center at (415) 221-4810 Ext. 3182.

Bryanne Patail at the National Center for Patient Safety (NCPS) at (734) 930-5890.

Attachments:
1) Boston Scientific Urgent Medical Device Information (Update to May, 2006 Product Advisory) dated January 4, 2008
2) VA National ICD Surveillance Center Memo dated January 24, 2008
3) Instructions to access the VA National ICD Surveillance Center Web portal

AL08-07

ATTACHMENT 1

URGENT MEDICAL DEVICE INFORMATION
Update to May, 2006 ***Product Advisory***
January 4, 2008

Boston Scientific

Cardiac Rhythm Management
4100 Hamline Avenue North
St. Paul, MN 55112-5798
www.bostonscientific.com

Summary

Issue: Repetitive mechanical stress applied to the titanium case can induce component damage and device malfunction in certain ICD and CRT-D devices implanted subpectorally with the serial number facing the ribs (susceptible orientation shown in Figure 2). Devices implanted subcutaneously or in a subpectoral position with the serial number facing away from the ribs are not included in this advisory. **This update identifies additional VITALITY® ICD models (Table 1) that are also subject to this failure mechanism if implanted in a susceptible orientation.**

Frequency: A total of 13 failures have been confirmed from an estimated 950 devices implanted in a susceptible orientation. The failure rate prediction is estimated to be 3% to 4% at 60 months.

Consequence: Loss of shock therapy, loss of pacing therapy (intermittent or permanent), or loss of telemetry communications.

Actions: Review patient records to determine if device was implanted subpectorally. Use an AP radiograph to determine specific device orientation. If a subpectoral implant is in a susceptible orientation, consider repositioning or replacement for physically active patients or for patients who regularly need device therapy. Follow patients with susceptible devices at 3-month intervals in accordance with device labeling.

Dear Doctor,

On May 12, 2006, Boston Scientific CRM issued a ***Product Advisory*** describing the potential for device malfunction in certain ICDs and CRT-Ds when implanted subpectorally with the serial number facing the ribs. Further clinical experience and testing indicate that additional VITALITY device models are also subject to this failure mechanism (Table 1).

Description of Issue

Accelerated life testing has shown that repetitive mechanical stress applied to the serial number side of the titanium case can induce component damage and device malfunction. This has occurred *only* when the device was implanted subpectorally with the serial number facing the ribs (Figure 2).

Figure 1. Optimal orientation for subpectoral implants. Leads exit in a counter clockwise direction. Serial number is facing *away* from the ribs.

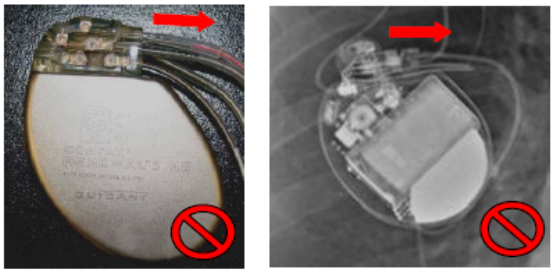


Figure 2. Photo and X-ray. Avoid this orientation for subpectoral implants. Leads exit in a clockwise direction. Serial number is facing the ribs.

Devices Affected

Table 1. Model numbers potentially affected if implanted subpectorally with serial number facing the ribs.

May 12, 2006 Population*	
CONTAK RENEWAL® 3 & 3 HE	H170/H173/H175/H177/H179
CONTAK RENEWAL 3 AVT & 3 AVT HE	M150/M155/M157/M159
CONTAK RENEWAL 4 & 4 HE	H190/H195/H197/H199
CONTAK RENEWAL 4 AVT & 4 AVT HE	M170/M175/M177/M179
VITALITY DR HE	T180
January 4, 2008 Population*	
VITALITY 2 EL DR/VR	T167/T177
VITALITY EL	T127
VITALITY DR+	1872

Notes:

*Not all devices are approved in all geographies.

Standard life VITALITY devices are not included in this advisory (one observation of this type in over 125,000 devices implanted to date).

A device model and serial number search tool is available at www.bostonscientific.com.

Clinical Implications
While there is no way to predict if or when a device in the susceptible orientation will fail, one or more of the following device behaviors indicate that a failure has occurred: loss of shock therapy, loss of pacing therapy (intermittent or permanent), loss of telemetry communications, beeping (16 tones every six hours), and display of a warning screen upon programmer interrogation.

Rate of Occurrence
Six additional failures (total of eight) have been confirmed from the May 12, 2006 population of 70,200 devices. Five failures have been confirmed from 24,700 devices in the January 4, 2008 population. There have been no reported patient deaths associated with this issue.

Because the implant orientation of devices is not reported to Boston Scientific, rate of occurrence or failure rate projections specific to a subpectoral implant with the serial number facing the ribs can only be estimated. ***If it is assumed that 1% of the total population is implanted in a susceptible orientation***:

- A total of 13 failures to date represents 1.4% of approximately 950 devices implanted in a susceptible orientation.
- The projected failure rate for devices implanted in the susceptible orientation is estimated to be 3% to 4% (28 to 38 devices) at 60 months for both the May 12, 2006 population and the January 4, 2008 population.

Recommendations
Patient management recommendations for both populations remain unchanged from May 12, 2006:

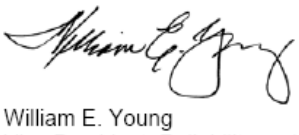
1. For patients implanted with a model listed in Table 1, review records to determine if the device was implanted subpectorally. Devices implanted subcutaneously are not subject to this advisory.
2. For subpectoral implants, use an AP radiograph to determine specific device orientation.
   - If the leads exit the pulse generator in a counter clockwise direction (Figure 1), this advisory does not apply and no change to your current patient management is necessary.
   - If the device is in a susceptible orientation (Figure 2),
     - Advise patient of the potential for device failure.
     - Follow patient at 3 month intervals in accordance with device labeling.
     - Consider device repositioning or replacement for physically active patients or for patients who regularly need device therapy.

     Where available, the LATITUDE® Patient Management System can enable remote follow-ups and facilitate patient monitoring between follow-ups.
3. For future implants, when considering subpectoral implantation of a device from any product family listed in Table 1, orient the device with the serial number facing away from the ribs (Figure 1).

Warranty Supplement Program
Boston Scientific's warranty supplement program, subject to certain conditions, provides full credit for the purchase of a Boston Scientific replacement device and an offer of up to $2500 patient assistance for unreimbursed medical expenses.

Further Information
Boston Scientific recognizes the impact of this communication on you and your patients and wants to reassure you that patient safety remains our primary concern. If you have any questions regarding this communication, please contact your local Boston Scientific CRM representative, United States Technical Services at 1.800.CARDIAC (227.3422) or European Technical Services at +32 2 416 7222.

Sincerely,



William E. Young
Vice President, Reliability and Quality Assurance
Boston Scientific Cardiac Rhythm Management

ATTACHMENT 1 (Continued)

PHYSICIAN DEVICE ADVISORY NOTICE

Advisory Date: May 12, 2006 and January 4, 2008

Manufacturer	Boston Scientific Corporation		
Product(s)	*Trade Name* May 12, 2006 Advisory CONTAK RENEWAL® 3/ 3 HE CONTAK RENEWAL 3 AVT/ 3 AVT HE CONTAK RENEWAL 4/ 4 HE CONTAK RENEWAL 4 AVT/ 4 AVT HE VITALITY® DR HE January 4, 2008 Advisory Update VITALITY DR+ VITALITY EL VITALITY 2 EL DR/VR	*Model Number* H170/H173/H175/H177/H179 M150/M155/M157/M159 H190/H195/H197/H199 M170/M175/M177/M179 T180 1872 T127 T167/T177	
Manufactured on or before (Date)			
Performance Failure	Loss of shock therapy, loss of pacing therapy (intermittent or permanent), or loss of telemetry communications		
Root Cause	Repetitive mechanical stress applied to the titanium case can induce component damage and device malfunction in devices implanted subpectorally with the serial number facing the ribs.		
Date Manufacturer Corrected Product Available	For future implants, when considering subpectoral implantation of a device from a product family listed above, orient the device with the serial number facing away from the ribs		
Has all affected product been retrieved?	☐ Yes	☒ No	See patient management recommendations

FDA CLASSIFICATION STATUS

Advisory classification	– Class II for May 12, 2006 population – Decision pending for January 4, 2008 population	
CLINICAL ACUITY	*(USA)*	*(Worldwide)*
a) Total number of units currently implanted	64,600	87,700
b) Estimated number of potentially affected devices of this mode	~700 in susceptible orientation (~1% of implanted population)	~950 in susceptible orientation (~1% of implanted population)
c) Estimated incidences of this performance failure over the projected life of the device	21 to 28 (3% to 4% of devices implanted in a susceptible orientation)	28 to 38 (3% to 4% of devices implanted in a susceptible orientation)
d) Total number with observed performance failure	6	13
% of performance failures d/b x 100 =	0.85%	1.4%
e) Mean age of product in implanted population	~32 months for May 12, 2006 population ~20 months for January 4, 2008 population	
f) Patient deaths reported	☐ Yes	☒ No
Number of deaths =	0 related to this issue	
g) Patient deaths with probable relationship to device failure	☐ Yes	☒ No
Number of deaths =	0	

* The data analysis provided in this report was generated by the manufacturer and may be subject to change

DEVICE COMPONENTS AT RISK OF PERFORMANCE FAILURE

☐ Battery Failure	☒ CRT (left ventricular pacing)
☐ Diagnostic Data Failure	☐ Lead Failure
☒ Brady Therapies (lower rate pacing)	☒ Internal component
☐ Brady Therapies (runaway pacing)	☐ EMI Susceptibility
☒ Tachy Therapies (ATP)	☒ Telemetry Failure
☒ Tachy Therapies (shock)	☐ Other

PATIENT MANAGEMENT RECOMMENDATIONS

Verify normal device function (at normal follow-up interval)	☒ Yes	☐ No
Verify normal device function (as soon as possible)	☐ Yes	☒ No

Patient management recommendations for both populations remain unchanged from May 12, 2006:

1. For patients implanted with advisory product, review records to determine if the device was implanted subpectorally. Devices implanted subcutaneously are not subject to this advisory.
2. For subpectoral implants, use an AP radiograph to determine specific device orientation.
   - ➢ If the leads exit the pulse generator in a counter clockwise direction (serial number facing ***away*** from the ribs), this advisory does not apply and no change to current patient management is necessary.
   - ➢ If the device is in a susceptible orientation (serial number facing the ribs),
     - Advise patient of the potential for device failure.
     - Follow patient at 3 month intervals in accordance with device labeling.
     - Consider device repositioning or replacement for physically active patients or for patients who regularly need device therapy.

     Where available, the LATITUDE® Patient Management System can enable remote follow-ups and facilitate patient monitoring between follow-ups.
3. For future implants, when considering subpectoral implantation, orient the device with the serial number facing away from the ribs.

Programming changes	☐ Required	☐ Recommended
If programming changes are required, specify changes: none required		
Accelerated device follow-up	☐	☒ No
Timeline - months:	3-month intervals per device labeling	

CONTACT

Boston Scientific Cardiac Rhythm Management

Technical Services – U.S.
1.800.CARDIAC (227.3422)
Tech.Services@guidant.com

Technical Services – Europe
+32 2 416 7222
eurtechservice@guidant.com

LATITUDE Clinician Support
1.800 CARDIAC (227-3422)
latitude@guidant.com

Patient Services
1.866.484.3268 – U.S. and Canada
001.651.582.4000 – International

DEPARTMENT OF VETERANS AFFAIRS
Medical Center
4150 Clement Street
San Francisco CA 94121

VA National ICD Surveillance Center

January 24, 2008

Dear colleagues:

On January 4, 2008, Boston's Scientific (Guidant) issued an Urgent Medical Device Information Notice that affects a subset of Boston Scientific (Guidant) ICDs and CRT-Ds. This document is to provide you with some general guidelines to deal with this safety problem. The present advisory is the same as the one issued by Boston Scientific on May 12, 2006; however, it has been updated to include additional Vitality ICD models that are also subject to this safety problem.

Device Model Affected:

Note: Not all devices are affected; susceptibility is determined by the implant configuration of the generators.

January 4, 2008 Population	
Device Model Name	Model Numbers
Vitality EL DR	T127
Vitality DR+	1872
Vitality 2 EL DR/VR	T167/T177
May 12, 2006 Population	
Device Model Name	Model Numbers
Contak Renewal 3 & 3 HE	H170/H173/H175/H177/H179
Contak Renewal 3 AVT & 3 AVT HE	M150/M155/M157/M159
Contak Renewal 4 & 4 HE	H190/H195/H197/H199
Contak Renewal 4 AVT & 4 AVT HE	M170/M175/M177/M179
Vitality DR HE	T180

The Problem:

The cause: Repetitive mechanical stress applied to the titanium case can induce component damage and device malfunction in devices implanted subpectorally with the serial number facing the ribs.

Reported incidence: No data from Boston Scientific because the implant orientation of devices is not reported to the manufacturer. A total of 13 device failures worldwide (5 out of 24,700 total devices in the present population) have been reported to date. Boston Scientific projected a failure rate for devices implanted in the susceptible orientation to be 3-4% (assuming 1% implantations in the susceptible orientation).

Boston Scientific reported no deaths or serious injuries in association with this recall.

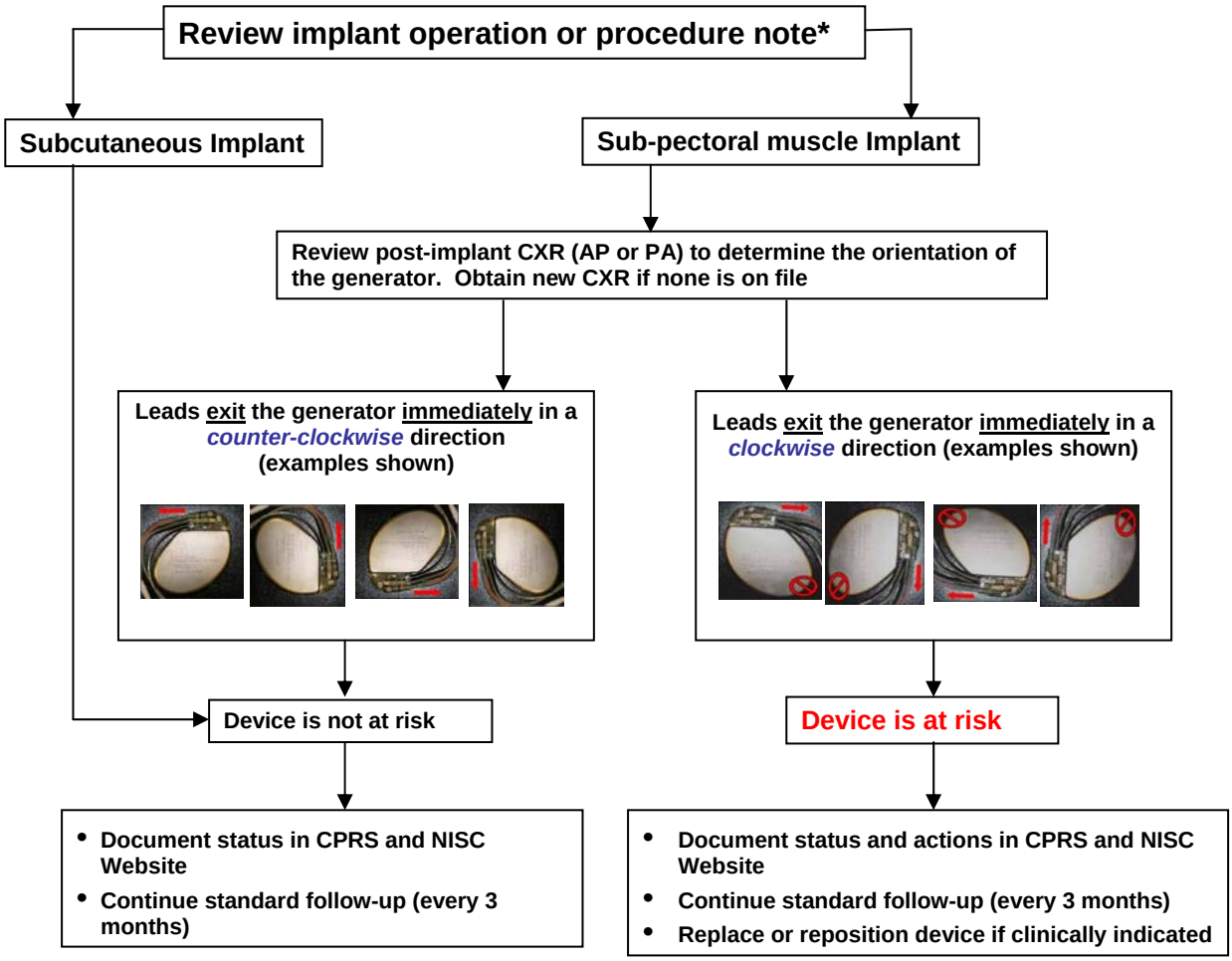
Potential adverse consequences of the problem:

- Unpredictable loss of shock therapy, loss of pacing therapy (intermittent or permanent), loss of telemetry communications, beeping (16 tones every six hours), and display of a warning screen upon programmer interrogation.

ATTACHMENT 2 (Continued)

Recommendations:

- The most important thing to do is to identify if patients implanted with a model listed above are susceptible to this advisory. Only devices implanted under the sub-pectoral muscles with the serial number facing the ribs are susceptible to this advisory. Within 90 days, use the following algorithm to identify susceptible devices.



* An alternative starting point is to review the post-op CXR to determine how the leads exit the generator. If they exist in a counter-clockwise direction, the device is not at risk, no matter what the location (subcutaneous or sub-pectoral) is.

If the operation or procedure note did not identify if the device was a sub-pectoral implantation, examination of the pocket in the clinic may be helpful in many cases. If the generator location still cannot be ascertained, it is best to treat it as a device at risk.

- Continue standard regular monitoring (clinic and remote) of the affected devices. To enroll patients in the LATITUDE Patient Management System via the VA National ICD Surveillance Center (NISC), go to its Web site (https://icdpm.sanfrancisco.med.va.gov). Most of the patients are already in the NISC database.
- However, in physically active patients or for patients who regularly need device therapy (tachy or brady), consider device repositioning or replacement.

ATTACHMENT 2 (Continued)

- Discuss this safety issue with your patients within 90 days of the issuance of this Alert, or as soon as you can. Document your actions in CPRS and update your patient information on the NISC website. A new Safety Alert Management Utility module has been added to the VA National ICD Surveillance website to assist you to identify and track your actions steps in response to the recall. See Attachment 3 for instruction.
- For future implants of the involved models, consider subcutaneous implantation or orienting the device with the serial number facing away from the ribs for subpectoral implantation.
- These recommendations are only suggestions and are not binding. We have to evaluate individual patient's clinical conditions, advise the patients of the risks (especially infection associated with device replacement or repositioning) and benefits of specific treatment option compared to the level of device performance as reported and arrive at the best course of action. As always, you should make the final determination on a case-by-case basis regarding the appropriate action for your patients.

Ed Keung, MD
Director, VA National ICD Surveillance Center
Ph: 415-221-4810, extension 3182
Edmund.Keung@va.gov

ATTACHMENT 3

Instructions on how to access the VA National ICD Surveillance center database and on using the Safety Alerts and Recalls Module to manage the recall. Please note that you can use the same ICD and Pacemaker Web portal as your own device database.

Perform the following steps to access your list of patient with the affected devices at the VA National ICD Surveillance Center Website. We created a new module to assist you to manage safety alerts and recalls:

1. VA intranet URL: https://ICDPM.sanfrancisco.med.va.gov

2. You have to register as a user first. Len Roberts, our administrator (Leonard.Roberts@va.gov) will review the information you provided and grant you access within 24 hours or less.

3. After you log in, click on <Safety Alerts and Recall> and <Alert Management Utility>. (See screen shot on the following page)

4. Select, in order: (See screen shot on the following page)

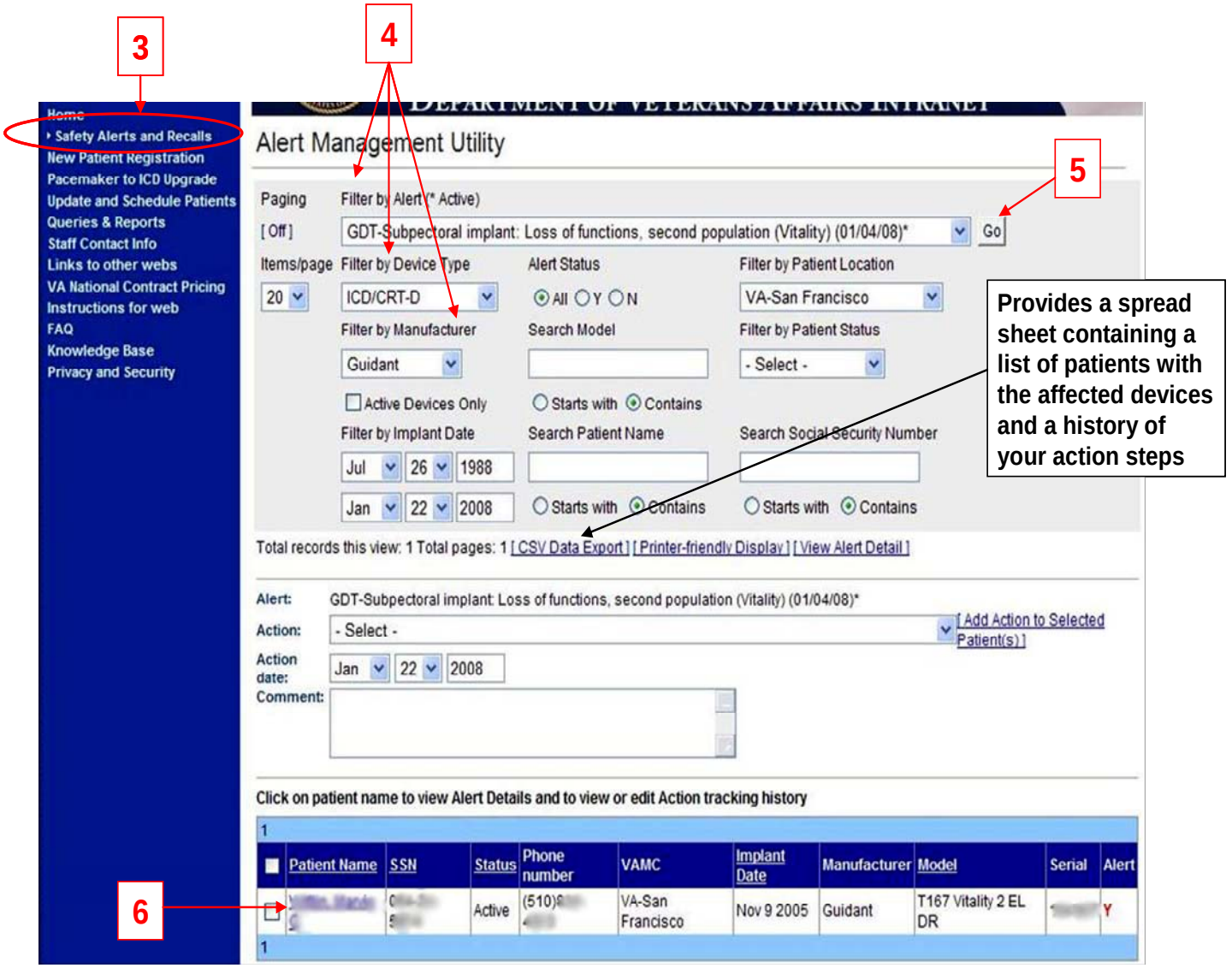
    a. ICD/CRT-D from the Filter by Device Type dropdown list
    b. Guidant from the Filter by Manufacturer dropdown list
    c. Select GDT-Subpectoral implant: Loss of functions, second population (Vitality) (01/04/08) from the Filter by Alert dropdown list
    To retrieve the first population, select GDT-Subpectoral implant: Loss of functions (Vitality, Renewal) (05/21/06)

5. Click "Go" to obtain your list (See screen shot on the following page)

The device alert status is listed in the far right corner under the column heading Alert (Y=Yes). Do not forget that there may be more than one page for the list, depending on how many patients you have. You can export the table to an Excel spreadsheet by clicking on the [CSV Data Export] button or just print it. (See screen shot on the following page)

The medical centers listed under the column VAMC are the hospitals where they had their device implanted or the follow-up clinics, according the records of the National ICD Surveillance Center and Medtronic.

ATTACHMENT 3 (Continued)

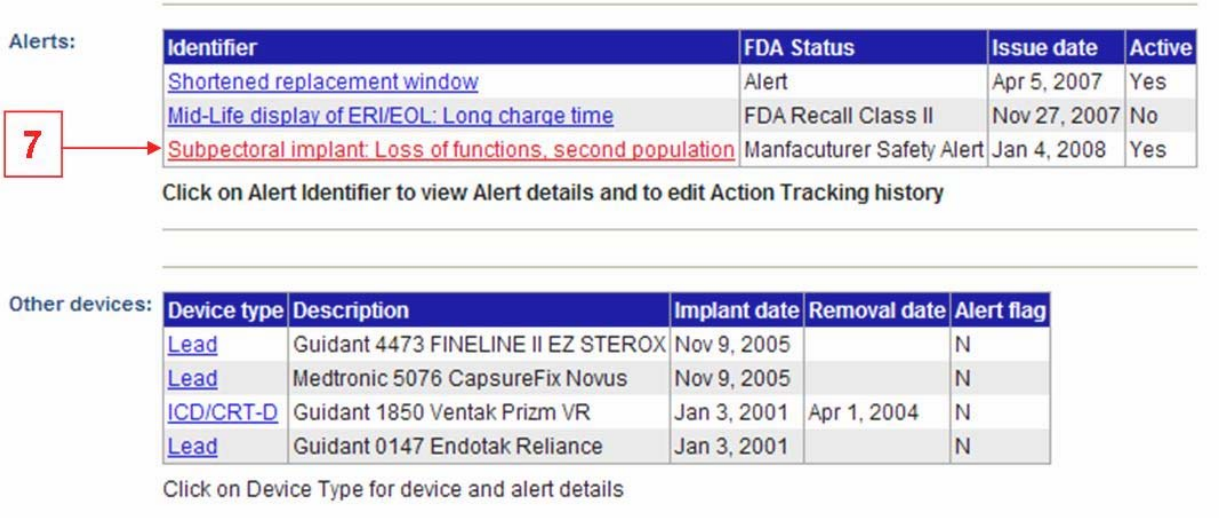


If you choose to use the Alert Management Utility Module to assist you in tracking and managing the recall, please follow the instructions below.

6. Click on a patient's name in the above list table and you will be taken to page 1 of the patient's detail alert page.

7. Click on the appropriate Alert Identifier (if there is more than one alert affecting the device). Clicking on the Alert will allow you to view the alert details and enter your actions in response to the alert. (See the screen shot on the following page)

ATTACHMENT 3 (Continued)



8. Click on the Action dropdown manual to select the alert action (see screen shot on the following page) accomplished and enter its appropriate Action date and Comment.

9. Click the [Add Action] button (see screen shot on the following page) to a link this action to the patient. Repeat #8 and #9 for each applicable action step.

10. Click the [Plain text summary] button (see screen shot on the following page) to obtain a text-file of the information displayed on this page. The content can be copied and pasted onto a CPRS progress note for record keeping.

ATTACHMENT 3 (Continued)