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Ralph Nader, Founder

July 6, 1994

Dear Pedicle Screw Implantee:

Public Citizen's Health Research Group is conducting a confidential survey of people who have been implanted with pedicle screws in their spines. We are a non-profit, consumer research and advocacy organization that provides advice and oversight regarding drugs, medical devices, health services and occupational health. We received your name from a support group in your area.

The Food and Drug Administration is holding hearings this month (July 21, 22) regarding the possible reclassification of pedicle spinal fixation devices into class II devices, which would allow the manufacturers to market them for use in the pedicle without being required to provide evidence of their safety and effectiveness. We are opposed to this reclassification, and wish to present data about the experiences which many people have had, as a result of being implanted with the pedicle screws.

Please take the time to complete the enclosed survey. The information you provide will be important to our research effort, and will be kept strictly confidential, as far as disclosing any information which could identify a specific patient. We will compile the data and present it at the FDA meeting, as well as send you a copy of our completed report. Please return the survey as soon as possible, as time is running out before the hearings. Only if we get your response by July 18th can we use it in compiling our results. We have enclosed a stamped and addressed envelope for your convenience. If questions arise, or if you become aware of other support groups that we can contact, please call Joanne Mott at (202) 833-3000. Thank you.

Sidney M. Wolfe, M.D.
Director

Joanne C. Mott, M.P.H.
Device Researcher

PUBLIC CITIZEN HEALTH RESEARCH GROUP

SURVEY OF PEDICLE SCREW RECIPIENTS

Name:

Age:

Sex:

Occupation:

Phone Number:

1. What was the date (month and year) of your first episode of back pain?
2. What were the symptoms associated with your back problem?
3. What was your back problem diagnosed as?
4. When was your problem first diagnosed by a physician (month and year)?
5. What was his/her subspecialty?
6. What was the date (month and year) of your first back surgery?
7. What was the diagnosis?
8. What was the operation?
9. What was the date (month and year) of your first surgery where a pedicle screw was inserted (if this date is different from date of question #6)?
10. What was the implanting surgeon's opinion about the reason you needed this surgery?
11. Were you ever informed by the implanting surgeon or the hospital, that the use of a bone screw in the pedicle of the spine was experimental?
12. How many total back surgeries have you had?

13. In how many of the total back surgeries did you have a pedicle screw(s) inserted?
14. How many pedicle screws were inserted in each episode of back surgery?
15. How many pedicle screws have you had explanted (taken out)?
16. What has happened to the pedicle screws which were inserted? (check all that apply). broken displaced
 explanted nothing other (explain).
17. How many years did you live with pedicle screws implanted in your spine?
18. On a scale of 1 to 10, how much has your injury or disability worsened, as a result of being implanted with pedicle screws (1 being not at all, 10 being very much)?
19. Did your physician or you report your problem with the pedicle screw to the (a) FDA (b) manufacturer (c) both (d) neither (e) do not know (circle).

OPTIONAL QUESTIONS (need not answer):

- A. Who was the doctor that diagnosed your original back problem (first and last name; city and state)?
- B. Who was the doctor(s) who performed the back surgery where a pedicle screw(s) was inserted (first and last name(s); city and state)?
- C. At what hospital (name and city) did you have your pedicle screw(s) inserted?

Please return this questionnaire in the enclosed self-addressed stamped envelope. You must mail it by July 15 for us to compile the data in time for the FDA hearing.