

BMP2 vs. Autograft for Critical Size Tibial Defects Follow-up Clinical Assessment

To be completed by the PHYSICIAN

Patient Study Number	Completed By: _____ Clinic: _____
Visit Date (MM/DD/YY) ____ / ____ / ____	Visit Schedule (check appropriate box) <input type="checkbox"/> 2 weeks <input type="checkbox"/> 6 weeks <input type="checkbox"/> 12 weeks <input type="checkbox"/> 18 weeks <input type="checkbox"/> 6 mo <input type="checkbox"/> 12 mo

Directions: Answer every question by filling in the correct circle or writing in the information. If you need to change an answer, completely erase or cross out the incorrect mark, initial, and fill in the correct information. **Mark only one answer for each question unless otherwise instructed. Shade circles like this: ●**

Please answer questions 01-03 at one follow-up only.

01. Date of definitive surgery (MM/DD/YY)

____ / ____ / ____

02. Date of definitive wound closure (MM/DD/YY)

____ / ____ / ____

03a. Type of definitive wound closure (Mark all that apply)

- ☐ Primary
- ☐ STSG
- ☐ Flap (Specify in 3b.)
- ☐ VAC assisted

b. If "Flap", specify type

- ☐ Local muscle
- ☐ Fasciocutaneous
- ☐ Free

04. Surgical procedures performed since last follow-up

- ☐ Yes
- ☐ No (Skip to question 7)

05. If "Yes", specify procedure and date performed

(Mark all that apply)

a. Procedure

- ☐ Dynamization
- ☐ Exchange nail
- ☐ Irrigation and debridement
- ☐ Remove painful implant - nail
- ☐ Remove painful implant – plate
- ☐ Remove painful implant – screws only
- ☐ Other (Specify below)

b. Date

(MM/DD/YY)

____ / ____ / ____
____ / ____ / ____
____ / ____ / ____
____ / ____ / ____
____ / ____ / ____
____ / ____ / ____
____ / ____ / ____

06. Complications since last follow-up

- ☐ Yes (Complete Adverse Event Form)
- ☐ No

Physical Exam

07a. Rotational alignment of affected extremity

- ☐ Normal (Skip to question 09)
- ☐ Internally rotated
- ☐ Externally rotated

b. If "Internally" or "Externally" rotated, specify
degrees of rotation ____ °

08a. Leg length discrepancy

- ☐ None (Skip to question 10)
- ☐ Affected leg shorter than unaffected leg
- ☐ Affected leg longer than unaffected leg

b. If "Short" or "Long", specify discrepancy
____ mm

For questions 09-12, fill in degree and either a positive (+) or negative (-) sign in the parenthesis.

09. Knee extension (0 = full extension, (+) = hyperextension)

- a. Active () _____°
- b. Passive () _____°

10. Knee flexion

- a. Active () _____°
- b. Passive () _____°

11. Ankle dorsiflexion (0 = neutral, (+) = dorsiflexion)

- a. Active () _____°
- b. Passive () _____°

12. Ankle plantarflexion

- a. Active () _____°
- b. Passive () _____°

13. Sensation at time of examination

Location	Normal	Diminished	Absent
a. Superficial peroneal	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Deep peroneal nerve	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Posterior tibial nerve	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please continue on next page

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14. Manual muscle test (Using the guide below mark the one grade that best applies to the muscle in question)

<u>Muscle Group</u>	0	1	2	3	4	5
a. Quadriceps	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Ankle dorsiflexors	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Manual Muscle Test

Grade 5: Maximum resistance, full ROM

Grade 4: Strong to moderate resistance, full ROM

Grade 3: Full ROM against growth

Grade 2: Gravity eliminated, full or partial ROM

Grade 1: Gravity eliminated, muscles palpable

Grade 0: Gravity eliminated, no contraction

15. Returned to pre-injury weight bearing status

☐ Yes ☐ No

16. How much weight bearing has the patient been doing in the last 2 weeks?

- ☐ Weight bearing prevented due to other injuries
- ☐ None
- ☐ Toe touch
- ☐ Partial weight bearing
- ☐ Full weight bearing as tolerated

17a. Recommended weight bearing status (Current visit)

- ☐ Weight bearing prevented due to other injuries
- ☐ None
- ☐ Toe touch
- ☐ Partial weight bearing (Specify below)
- ☐ Full weight bearing as tolerated

b. If "Partial weight bearing", please specify

_____ lbs

18. Recommended ambulatory support (Current visit)

- | | |
|--|----------------------------------|
| <input type="radio"/> Unable to ambulate | <input type="radio"/> One crutch |
| <input type="radio"/> Walker | <input type="radio"/> Cane |
| <input type="radio"/> Two crutches | <input type="radio"/> None |

19. On a scale from 0 to 10, mark the patient's average level of pain at the fracture site/knee during weight bearing in the past week, with 0 being none and 10 being unbearable.

0 1 2 3 4 5 6 7 8 9 10

None | -○-○-○-○-○-○-○-○-○-○- | Unbearable

20. On a scale from 0 to 10, mark the patient's average level of pain during daily activities in the past week, with 0 being none and 10 being unbearable.

0 1 2 3 4 5 6 7 8 9 10

None | -○-○-○-○-○-○-○-○-○-○- | Unbearable

21. Frequency of pain medication use

- ☐ Never (Skip to question 24)
- ☐ Less than once a week
- ☐ Once a week
- ☐ Several times a week
- ☐ Daily
- ☐ Multiple times per day

22a. Type of pain medications used (Mark all that apply)

- ☐ Acetaminophen
- ☐ Narcotics
- ☐ NSAIDs
- ☐ Other (Specify): _____

23. Patient's Workers' Compensation status

- ☐ Currently seeking Workers' Compensation
- ☐ Workers' Compensation case settled
- ☐ Not planning on applying for Workers' Compensation

24. Patient's litigation status

- ☐ Currently involved in litigation
- ☐ Litigation settled
- ☐ Not planning on pursuing litigation

Radiographic Evaluation

25. Alignment on post-operative films

- a. _____° ☐ Varus or ☐ Valgus
- b. _____° ☐ Anterior angulation or ☐ Posterior angulation

26. Presence of callus

<u>Location</u>	<u>None</u>	<u>Some</u>	<u>Bridging</u>	<u>Remodeled</u>
a. Medial cortex	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Lateral cortex	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Anterior cortex	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
d. Posterior cortex	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

27. Radiographically healed

- ☐ Yes ☐ No

BMP2 vs. Autograft for Critical Size Tibial Defects SF-12v2TM Health Survey

(SF-12 v2 Standard, US Version 2.0)

To be completed by the PATIENT

Patient Study Number	Completed By: _____ Clinic: _____
Visit Date (MM/DD/YY) ____ / ____ / ____	Visit Schedule (check appropriate box) <input type="checkbox"/> 6 mo <input type="checkbox"/> 12 mo

Directions: This survey asks for your views about your health. This information will help you keep track of how you feel and how well you are able to do your usual activities. If you are unsure about how to answer a question, please give the best answer you can. **Mark only one answer for each question unless otherwise instructed. Shade circles like this:**

	Excellent	Very Good	Good	Fair	Poor
01. In general, would you say your health is:	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>The following questions are about activities you might do during a typical day. Does <u>your health now limit you</u> in these activities? If so, how much?</i>					
02. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		
03. Climbing <u>several</u> flights of stairs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>		
<i>During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of your physical health</u>?</i>					
04. Accomplished less than you would like	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
05. Were limited in the <u>kind</u> of work or other activities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<i>During the <u>past 4 weeks</u>, how much of the time have you had any of the following problems with your work or other regular daily activities <u>as a result of any emotional problems</u> (such as feeling depressed or anxious)?</i>					
06. Accomplished less than you would like	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
07. Did work or activities <u>less carefully than usual</u>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
08. During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?	Not at all <input type="radio"/>	A little bit <input type="radio"/>	Moderately <input type="radio"/>	Quite a bit <input type="radio"/>	Extremely <input type="radio"/>
<i>These questions are about how you feel and how things have been with you during the <u>past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>...</i>					
09. Have you felt calm and peaceful?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. Did you have a lot of energy?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. Have you felt downhearted and depressed?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting friends, relatives, etc.)?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

***BMP2 vs. Autograft for
Critical Size Tibial Defects
Short Musculoskeletal
Function Assessment***
To be completed by the PATIENT

Patient Study Number	Completed By: _____ Clinic: _____
Visit Date (MM/DD/YY) ____ / ____ / ____	Visit Schedule (<i>check appropriate box</i>) <input type="checkbox"/> 6 mo <input type="checkbox"/> 12 mo

Directions: We are interested in finding out how you are managing with your injury or arthritis this week. We would like to know about any problems you may be having with your daily activities because of your injury or arthritis. Please answer each question by shading in the circle corresponding to the choice that best describes you.. **Mark only one answer for each question unless otherwise instructed. Shade circles like this: ●**

These questions are about how much difficulty you may be having this week with your daily activities because of your injury or arthritis.

	<u>Not at all difficult</u>	<u>A little difficult</u>	<u>Moderately difficult</u>	<u>Very difficult</u>	<u>Unable to do</u>
01. How difficult is it for you to get in or out of a low chair?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
02. How difficult is it for you to open medicine bottles or jars?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
03. How difficult is it for you to shop for groceries or other things?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
04. How difficult is it for you to climb stairs?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
05. How difficult is it for you to make a tight fist?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
06. How difficult is it for you to get in or out of the bathtub or shower?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
07. How difficult is it for you to get comfortable to sleep?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
08. How difficult is it for you to bend or kneel down?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
09. How difficult is it for you to use buttons, snaps, hooks, or zippers?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. How difficult is it for you to cut your own fingernails?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. How difficult is it for you to dress yourself?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. How difficult is it for you to walk?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. How difficult is it for you to get moving after you have been sitting or lying down?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. How difficult is it for you to go out by yourself?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. How difficult is it for you to drive?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
16. How difficult is it for you to clean yourself after going to the bathroom?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
17. How difficult is it for you turn knobs or levers, for example, open doors, roll down car windows?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
18. How difficult is it for you to write or type?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
19. How difficult is it for you to pivot?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
20. How difficult is it for you to do your usual physical recreational activities, such as bicycling, jogging, or walking?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
21. How difficult is it for you to do your usual leisure activities, such as hobbies, crafts, gardening, card playing, going out with friends?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
22. How much difficulty are you having with sexual activity?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
23. How difficult is it for you to do <u>light</u> housework <u>or</u> yardwork, such as dusting, washing dishes, or watering plants?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
24. How difficult is it for you to do <u>heavy</u> housework <u>or</u> yardwork, such as washing floors, vacuuming, or mowing lawns?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
25. How difficult is it for you to do your usual work, such as a paid job, housework, volunteer activities?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Please continue on next page

***BMP2 vs. Autograft for
Critical Size Tibial Defects
Short Musculoskeletal
Function Assessment***
To be completed by the PATIENT

Patient Study Number	Completed By: _____ Clinic: _____
Visit Date (MM/DD/YY) ____ / ____ / ____	Visit Schedule (<i>check appropriate box</i>) <input type="checkbox"/> 6 mo <input type="checkbox"/> 12 mo

These next questions ask how often you are experiencing problems this week because of your injury or arthritis

	<u>None of the time</u>	<u>A little of the time</u>	<u>Some of the time</u>	<u>Most of the time</u>	<u>All of the time</u>
26. How often do you walk with a limp?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
27. How often do you avoid using your painful limb(s) or back?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
28. How often does your leg lock or give-way?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
29. How often do you have problems with concentration?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
30. How often does doing too much in one day affect what you do the next day?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
31. How often do you act irritable toward those around you, for example, snap at people, give sharp answers, or criticize easily?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
32. How often are you tired?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
33. How often do you feel disabled?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
34. How often do you feel angry or frustrated that you have this injury or arthritis?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

These next questions are about how much you are bothered by problems you are having this week due to your injury or arthritis

How much are you bothered by:	<u>Not bothered at all</u>	<u>A little bothered</u>	<u>Moderately bothered</u>	<u>Very bothered</u>	<u>Extremely bothered</u>
35. Problems using your hands?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
36. Problems using your back?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
37. Problems doing work around your home?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
38. Problems with bathing, dressing, toileting or other personal care?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
39. Problems with sleep and rest?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
40. Problems with leisure or recreational activities?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
41. Problems with your friends, family or other important people in your life?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
42. Problems with thinking, concentrating or remembering?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
43. Problems adjusting or coping with your injury or arthritis?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
44. Problems doing your usual work?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
45. Problems with feeling dependent on others?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
46. Problems with stiffness and pain?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

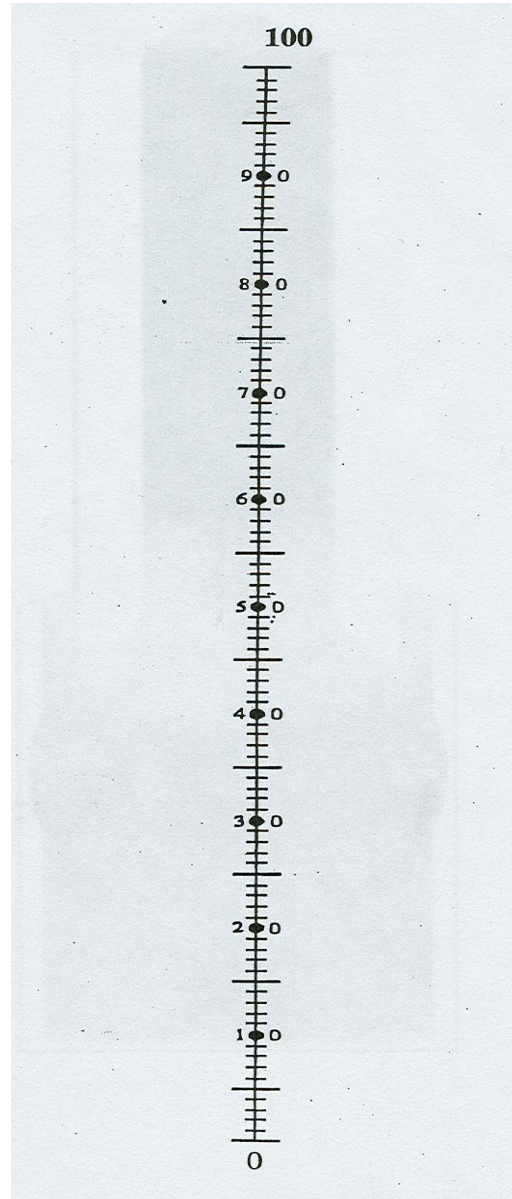
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***BMP2 vs. Autograft for
Critical Size Tibial Defects***
Visual Analog Scale
 To be completed by the PATIENT

Patient Study Number	Completed By: _____ Clinic: _____
Visit Date (MM/DD/YY) ____ / ____ / ____	Visit Schedule (<i>check appropriate box</i>) <input type="checkbox"/> 2 weeks <input type="checkbox"/> 6 weeks <input type="checkbox"/> 12 weeks <input type="checkbox"/> 18 weeks <input type="checkbox"/> 6 mo. <input type="checkbox"/> 12 mo.

Directions: To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0. We would like you to indicate on this scale how good or bad your own health is **NOW**, in your opinion. Please do this by placing an **X** on the scale below.

BEST IMAGINABLE HEALTH STATE (100)



WORST IMAGINABLE HEALTH STATE (0)

***BMP2 vs. Autograft for
Critical Size Tibial Defects
Sickness Impact Profile***
To be completed by the PATIENT

Patient Study Number	Completed By: _____ Clinic: _____
Visit Date (MM/DD/YY) ____ / ____ / ____	Visit Schedule (<i>check appropriate box</i>) <input type="checkbox"/> 6 mo <input type="checkbox"/> 12 mo

Directions: Please read the entire introduction before you read the questionnaire. It is very important that everyone taking the questionnaire follows the same instructions.

Introduction

You have certain activities that you do in carrying on your life. Sometimes you do all of these activities. Other times, because of your state of health, you don't do these activities in the usual way: you may cut some out; you may do some for shorter lengths of time; you may do some in different ways. These changes in your activities might be recent or longstanding. We are interested in learning about any changes that describe you today and are related to your state of health.

The questionnaire booklet lists statements that people have told us describe them when they are not completely well. Whether or not you consider yourself sick, there may be some statements that will stand out because they describe you today and are related to your state of health. As you read the questionnaire, think of yourself today. When you read a statement that you are sure describes you and is related to your health, place a check in the line to the right of the statement. For example:

I am not driving my car ✓

If you have not been driving for some time because of your health, and are still not driving today, you should respond to this statement.

On the other hand, if you never drive or are not driving today because your car is being repaired, the statement, "I am not driving my car" is not related to your health and you should not check it. If you simply are driving less, or are driving shorter distances, and feel that the statement only partially describes you, do not check it. In all of these cases you would leave the line to the right of the statement blank. For example:

I am not driving my car _____

Remember that we want you to check this statement only if you are sure it describes you today and is related to your state of health.

Read the introduction to each group of statements and then consider the statements in the order listed. While some of the statements may not apply to you, we ask that you please read all of them. Check those that describe you as you go along. Some of the statements will differ only in a few words, so please read each one carefully. While you may go back and change a response, your first answer is usually the best. Please do not read ahead in the booklet

Once you have started the questionnaire, it is very important that you complete it within one day (24 hours).

If you find it hard to keep your mind on the statements, take a short break and then continue. When you have read all of the statements on a page, put a check in the BOX in the lower right-hand corner. If you have any questions, please refer back to these instructions.

Please do not discuss the statements with anyone, including family members, while doing the questionnaire.

Now turn to the questionnaire booklet and read the statements. Remember, we are interested in the recent or longstanding changes in your activities that are related to your health.

PLEASE RESPOND TO (CHECK) ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

1. I spend much of the day lying down in order to rest _____
2. I sit during much of the day _____
3. I am sleeping or dozing most of the time – day and night _____
4. I lie down more often during the day in order to rest _____
5. I sit around half-asleep _____
6. I sleep less at night, for example, wake up too early,
don't fall asleep for a long time, awaken frequently _____
7. I sleep or nap more during the day _____

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON
THIS PAGE

☐

PLEASE RESPOND TO (CHECK) ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

1. I say how bad or useless I am, for example, that I am a burden on others _____
2. I laugh or cry suddenly _____
3. I often moan and groan in pain or discomfort _____
4. I have attempted suicide _____
5. I act nervous or restless _____
6. I keep rubbing or holding areas of my body that hurt or are uncomfortable _____
7. I act irritable and impatient with myself, for example, talk badly about myself, swear at myself, blame myself for things that happen _____
8. I talk about the future in a hopeless way _____
9. I get sudden frights _____

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

PLEASE RESPOND TO (CHECK) ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

1. I make difficult moves with help, for example, getting into or out of cars, bathtubs _____
2. I do not move into or out of bed or chair by myself but am moved by a person or mechanical aid _____
3. I stand only for short periods of time _____
4. I do not maintain balance _____
5. I move my hands or fingers with some limitation or difficulty _____
6. I stand up only with someone's help _____
7. I kneel, stoop, or bend down only by holding on to something _____
8. I am in a restricted position all the time _____
9. I am very clumsy in body movements _____
10. I get in and out of bed or chairs by grasping something for support or using a cane or walker _____
11. I stay lying down for most of the time _____
12. I change position frequently _____
13. I hold on to something to move myself around in bed _____

(Continued on next page)

(Continued from previous page)

- | | | |
|-----|---|-------|
| 14. | I do not bathe myself completely, for example, require assistance with bathing | _____ |
| 15. | I do not bathe myself at all, but am bathed by someone else | _____ |
| 16. | I use bedpan with assistance | _____ |
| 17. | I have trouble getting shoes, socks, or stockings on | _____ |
| 18. | I do not have control of my bladder | _____ |
| 19. | I do not fasten my clothing, for example, require assistance with buttons, zippers, and shoelaces | _____ |
| 20. | I spend most of the time partly undressed or in pajamas | _____ |
| 21. | I do not have control of my bowels | _____ |
| 22. | I dress myself, but do so very slowly | _____ |
| 23. | I get dressed only with someone's help | _____ |

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

THIS GROUP OF STATEMENTS HAS TO DO WITH ANY WORK YOU USUALLY DO IN CARING FOR YOUR HOME OR YARD. CONSIDERING JUST THOSE THINGS THAT YOU DO, PLEASE RESPOND TO (CHECK) ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH

1. I do work around the house only for short periods of time or rest often _____
2. I am doing less of the regular daily work around the house than I would usually do _____
3. I am not doing any of the regular daily work around the house that I would usually do _____
4. I am not doing any of the maintenance or repair work that I would usually do in my home or yard _____
5. I am not doing any of the shopping that I would usually do _____
6. I am not doing any of the house cleaning that I would usually do _____
7. I have difficulty doing handwork, for example, turning faucets, using kitchen gadgets, sewing, carpentry _____
8. I am not doing any of the clothes washing that I would usually do _____
9. I am not doing heavy work around the house _____
10. I have given up taking care of personal or household business affairs, for example, paying bills, banking, working on budget _____

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

PLEASE RESPOND TO (CHECK) ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

1. I am getting around only within one building _____
2. I stay within one room _____
3. I am staying in bed more _____
4. I am staying in bed most of the time _____
5. I am not now using public transportation _____
6. I stay home most of the time _____
7. I am only going to places with restrooms nearby _____
8. I am not going into town _____
9. I stay away from home only for brief periods of time _____
10. I do not get around in the dark or in unlit places
without someone's help _____

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON
THIS PAGE

☐

PLEASE RESPOND TO (CHECK) ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

1. I am going out less to visit people _____
2. I am not going out to visit people at all _____
3. I show less interest in other people's problems, for example, don't listen when they tell me about their problems, don't offer to help _____
4. I often act irritable toward those around me, for example, snap at people, give sharp answers, criticize easily _____
5. I show less affection _____
6. I am doing fewer social activities with groups of people _____
7. I am cutting down the length of visits with friends _____
8. I am avoiding social visits from others _____
9. My sexual activity is decreased _____
10. I often express concern over what might be happening to my health _____
11. I talk less with those around me _____
12. I make many demands, for example, insist that people do things for me, tell them how to do things _____
13. I stay alone much of the time _____

(Continued on next page)

(Continued from previous page)

14. I act disagreeable to family members, for example,
I act spiteful, I am stubborn _____
15. I have frequent outbursts of anger at family members,
for example, strike at them, scream, throw things
at them _____
16. I isolate myself as much as I can from the rest of
the family _____
17. I am paying less attention to the children _____
18. I refuse contact with family members, for example, turn
away from them _____
19. I am not doing the things that I usually do to take care of
my children or family _____
20. I am not joking with family members as I usually do _____

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON
THIS PAGE

☐

PLEASE RESPOND TO (CHECK) ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

1. I walk shorter distances or stop to rest often _____
2. I do not walk up or down hills _____
3. I use stairs only with mechanical support, for example, handrail, cane, crutches _____
4. I walk up or down stairs only with assistance from someone else _____
5. I get around in a wheelchair _____
6. I do not walk at all _____
7. I walk by myself but with some difficulty, for example, limp, wobble, stumble, have stiff leg _____
8. I walk only with help from someone _____
9. I go up and down stairs more slowly, for example, one step at a time, stop often _____
10. I do not use stairs at all _____
11. I get around only by using a walker, crutches, cane, walls, or furniture _____
12. I walk more slowly _____

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

PLEASE RESPOND TO (CHECK) ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

1. I walk shorter distances or stop to rest often _____
2. I have more minor accidents, for example, drop things, trip and fall, bump into things _____
3. I react slowly to things that are said or done _____
4. I do not finish things I start _____
5. I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things _____
6. I sometimes behave as if I were confused or disoriented in place or time, for example, where I am, who is around, directions, what day it is _____
7. I forget a lot, for example, things that happened recently, where I put things, appointments _____
8. I do not keep my attention on any activity for long _____
9. I make more mistakes than usual _____
10. I have difficulty doing activities involving concentration and thinking _____

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

PLEASE RESPOND TO (CHECK) ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

1. I am having trouble writing or typing _____
2. I communicate mostly by gestures, for example, moving head, pointing, sign language _____
3. My speech is understood only by a few people who know me well _____
4. I often lose control of my voice when I talk, for example, my voice gets louder or softer, trembles, changes unexpectedly _____
5. I don't write except to sign my name _____
6. I carry on a conversation only when very close to the other person or looking at him _____
7. I have difficulty speaking, for example, get stuck, stutter, stammer, slur my words _____
8. I am understood with difficulty _____
9. I do not speak clearly when under stress _____

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

THE NEXT GROUP OF STATEMENTS HAS TO DO WITH ANY WORK YOU USUALLY DO OTHER THAN MANAGING YOUR HOME. BY THIS WE MEAN ANYTHING THAT YOU REGARD AS WORK THAT YOU DO ON A REGULAR BASIS.

DO YOU USUALLY DO WORK OTHER THAN
MANAGING YOUR HOME?

YES

NO

IF YOU ANSWERED YES, GO ON TO THE NEXT PAGE

IF YOU ANSWERED NO:

ARE YOU RETIRED?

YES

NO

IF YOU ARE RETIRED, WAS YOUR RETIRE-
MENT RELATED TO YOUR HEALTH?

YES

NO

IF YOU ARE NOT RETIRED, BUT ARE
NOT WORKING, IS THIS RELATED TO
YOUR HEALTH?

YES

NO

NOW SKIP TO THE NEXT PAGE.

**IF YOU ARE NOT WORKING AND IT IS NOT BECAUSE OF
YOUR HEALTH, PLEASE SKIP THIS PAGE**

**NOW CONSIDER THE WORK YOU DO AND RESPOND TO (CHECK) ONLY
THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND
ARE RELATED TO YOUR STATE OF HEALTH. (IF TODAY IS A SATURDAY
OR SUNDAY OR SOME OTHER DAY THAT YOU WOULD USUALLY HAVE
OFF, PLEASE RESPOND AS IF TODAY WERE A WORKING DAY.)**

1. I am not working at all _____
(IF YOU CHECKED THIS STATEMENT, SKIP TO THE NEXT PAGE.)
2. I am doing part of my job at home _____
3. I am not accomplishing as much as usual at work _____
4. I often act irritable toward my work associates, for example,
snap at them, give sharp answers, criticize easily _____
5. I am working shorter hours _____
6. I am doing only light work _____
7. I work only for short periods of time or take frequent
rests _____
8. I am working at my usual job but with some changes,
for example, using different tools or special aids,
trading some tasks with other workers _____
9. I do not do my job as carefully and accurately as usual _____

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON
THIS PAGE

☐

THIS GROUP OF STATEMENTS HAS TO DO WITH ACTIVITIES YOU USUALLY DO IN YOUR FREE TIME. THESE ACTIVITIES ARE THINGS THAT YOU MIGHT DO FOR RELAXATION, TO PASS THE TIME, OR FOR ENTERTAINMENT. PLEASE RESPOND TO (CHECK) ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

1. I do my hobbies and recreation for shorter periods of time _____
2. I am going out for entertainment less often _____
3. I am cutting down on some of my usual inactive recreation and pastimes, for example, watching TV, playing cards, reading _____
4. I am not doing any of my usual inactive recreation and pastimes, for example, watching TV, playing cards, reading _____
5. I am doing more inactive pastimes in place of my other usual activities _____
6. I am doing fewer community activities _____
7. I am cutting down on some of my usual physical recreation or activities _____
8. I am not doing any of my usual physical recreation or activities _____

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

PLEASE RESPOND TO (CHECK) ONLY THOSE STATEMENTS THAT YOU ARE SURE DESCRIBE YOU TODAY AND ARE RELATED TO YOUR STATE OF HEALTH.

1. I am eating much less than usual _____
2. I feed myself but only by using specially prepared food or utensils _____
3. I am eating special or different food, for example, soft food, bland diet, low-salt, low-fat, low-sugar _____
4. I eat no food at all but am taking fluids _____
5. I just pick or nibble at my food _____
6. I am drinking less fluids _____
7. I feed myself with help from someone else _____
8. I do not feed myself at all, but must be fed _____
9. I am eating no food at all, nutrition is taken through tubes or intravenous fluids _____

CHECK HERE WHEN YOU HAVE READ ALL STATEMENTS ON THIS PAGE

☐

NOW, PLEASE REVIEW THE QUESTIONNAIRE TO BE CERTAIN YOU HAVE FILLED OUT ALL THE INFORMATION. LOOK OVER THE BOXES ON EACH PAGE TO MAKE SURE EACH ONE IS CHECKED SHOWING THAT YOU HAVE READ ALL OF THE STATEMENTS. IF YOU FIND A BOX WITHOUT A CHECK, THEN READ THE STATEMENTS ON THAT PAGE.

BMP2 vs. Autograft for Critical Size Tibial Defects Adverse Event Form

To be completed by the PHYSICIAN

Patient Study Number	Completed By: _____ Clinic: _____
Visit Date (MM/DD/YY) ____ / ____ / ____	Visit Schedule (As Needed)

01. Date of occurrence (MM/DD/YY)

____ / ____ / ____

02. Did this complication occur perioperatively?

☐ Yes ☐ No

03. Severity of the event

- ☐ Mild – does not interfere with ADL
- ☐ Moderate – interferes some with ADL
- ☐ Severe – incapacitating, unable to perform ADL

04. Type of complication/adverse event

- ☐ Surgical site / Orthopaedic (*Skip to question 07*)
- ☐ Systemic
- ☐ Other event (*Specify*): _____

05. If “Systemic” complication, specify below

- | | |
|---|---|
| <input type="radio"/> Anaphylactic reaction | <input type="radio"/> Neurological deficit |
| <input type="radio"/> Atelectasis | <input type="radio"/> Peripheral nerve injury |
| <input type="radio"/> Blood loss anemia | <input type="radio"/> Pneumonia |
| <input type="radio"/> Cardiovascular arrhythmia | <input type="radio"/> Pulmonary embolism |
| <input type="radio"/> Congestive heart failure | <input type="radio"/> Stroke/CVA |
| <input type="radio"/> DVT | <input type="radio"/> Thrombophlebitis |
| <input type="radio"/> GI bleeding | <input type="radio"/> Urinary tract infection |
| <input type="radio"/> Ileus | <input type="radio"/> Vascular injury |
| <input type="radio"/> Myocardial infarction | |
| <input type="radio"/> Other (<i>Specify</i>): _____ | |

06. Relationship of “Systemic” complication to surgery

- | | |
|--|--|
| <input type="radio"/> Definitely related | <input type="radio"/> Probably not related |
| <input type="radio"/> Possibly related | <input type="radio"/> Definitely not related |
| <input type="radio"/> Unknown | |

07. If “Surgical site/Orthopaedic” complication, specify below

- ☐ Compartment syndrome
- ☐ Construct loosening – proximal to fracture
- ☐ Construct loosening – distal to fracture
- ☐ Fractured implant – nail
- ☐ Fractured implant – plate
- ☐ Fractured implant – screw(s)
- ☐ Hematoma
- ☐ Infection – deep
- ☐ Infection – superficial
- ☐ Necrosis/would slough
- ☐ Non-union
- ☐ Painful implant – nail
- ☐ Painful implant – plate
- ☐ Painful implant – screw
- ☐ Peripheral nerve injury
- ☐ Peri-implant fracture
- ☐ Other (*Specify*): _____