



Orthopaedic Surgery
Southern Cross North Harbour
P.O. Box 101-488
North Shore Mail Centre,
Auckland City, 0745
Telephone: (09) 925 4400
Facsimile: (09) 925 4434

Study Participant Pain Diary

Intraosseous Regional Administration of Diclofenac (IRAD) in Primary TKA Study

**A prospective, double-blinded, randomised controlled trial of Intraosseous
Regional Diclofenac vs Intravenous Diclofenac for Postoperative Pain
Management in Primary Total Knee Arthroplasty**

Patient Study ID Number:

Date of study enrolment:

Date of operation:

Date of discharge from hospital:

Dates of follow up clinics: 2-week -

6-week -

Investigator Signature Upon Completion:

Date of Study Completion:

Table of Contents

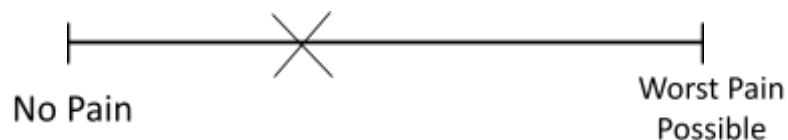
Information for Patients	3
VAS Pain Scores - Hours Post-Op	4
Quality of Recovery (QoR-15) Survey - Post-Op Day 1	6
VAS Pain Scores - Days Post-Op	7
Daily Opioid Pain Medication Used	10
Numerical Rating Scale for Effect of Pain on Walking Ability and Sleep	11
Numerical Rating Scale for Patient Satisfaction of their Knee Replacement	13
Recording Adverse Events	14

Information for Patients

This Pain Diary is for you to complete as part of the study. The purpose of the Pain Diary is for you to make recordings for the measurements explained below. The information from your Pain Diary will be collated and used in the results of this study.

Recording “Pain Levels”

This will be based on a ‘visual analogue scale’ (VAS), simply put a scale ranging from ‘No Pain’ to ‘Worst Pain Possible’ (example shown below). At each specified time interval you will have to mark a cross on the scale for how much pain you are experiencing, then measure with a ruler the distance between ‘No Pain’ and the cross, then record the (VAS) measurement in millimetres (mm). In the beginning nursing staff can help advise you. The time intervals include 1 hour, 2 hours, 3 hours, 4 hours, 5 hours, 12 hours, and 24 hours after your operation, as well as twice daily measurements starting from the day after your operation (Post-Op Day 1) to the 7th day after your operation (Post-Op Day 7). These measurements will be at **8am and 5pm**.



VAS Pain (mm): _____

Recording Pain Medication Used

You will be required to record the total amount of voluntary opioid pain medications (Morphine, Sevredol, Oxycodone etc.) you are using per day in the tables provided. This will begin from the day of your surgery (Post-Op Day 0), until day 7 after your surgery (Post-Op Day 7) Nursing staff will initially provide assistance until you are able to do so independently.

Recording Scores for Walking Ability/Gait and Sleep

These scores will represent how pain has interfered with your walking ability and sleep over the past 24 hours. You will have to record a score on a scale from 0 to 10 (Numerical Rating Scale), from ‘does not interfere’ to ‘completely interferes’.

Quality of Recovery (QoR-15) Survey

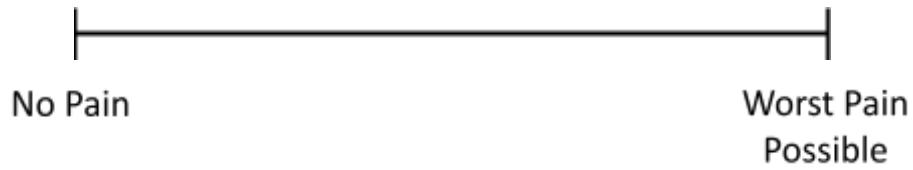
You will be required to complete the QoR-15 survey the day following your operation. This measures the quality of recovery after anaesthesia and is an indicator of early postoperative health.

Recording Adverse Events

This section will be used by participants as well as researchers/study doctors. If an adverse event, that is any undesirable clinical event (such as a side effect of a medication, or technical procedure error etc), were to occur, patients or researchers/study doctors (where indicated) may record the details of the event in a table.

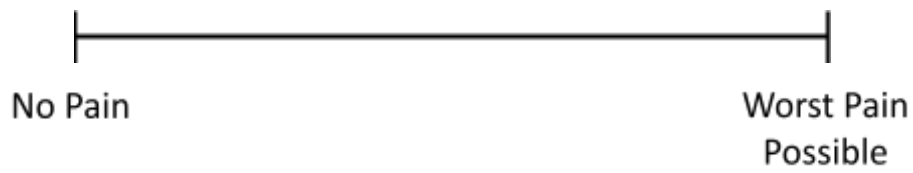
VAS Pain Scores - Hours Post-Op

1 Hour Post-Op



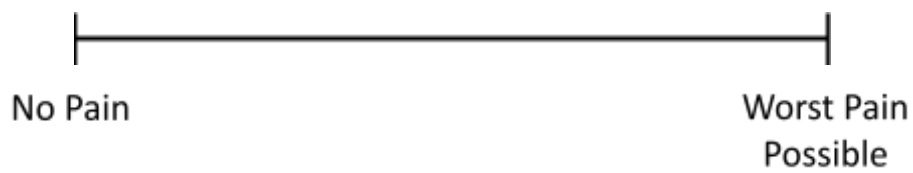
VAS Pain (mm): _____

2 Hours Post-Op



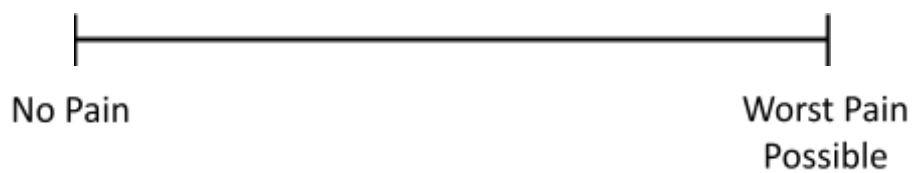
VAS Pain (mm): _____

3 Hours Post-Op



VAS Pain (mm): _____

4 Hours Post-Op



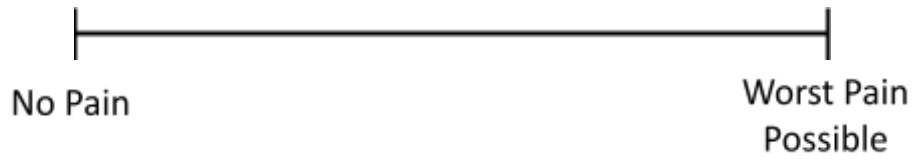
VAS Pain (mm): _____

5 Hours Post-Op



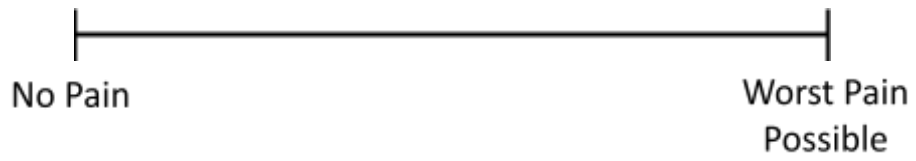
VAS Pain (mm): _____

12 Hours Post-Op



VAS Pain (mm): _____

24 Hours Post-Op



VAS Pain (mm): _____

Table 1 - VAS Pain Hours 1-24 Post-Op

Hours Post-Op	1	2	3	4	5	6	12	24
VAS Pain (mm)								

Quality of Recovery (QoR-15) Survey - Post-Op Day 1

PART A

How have you been feeling in the last 24 hours?

(0 to 10, where: 0 = none of the time [poor] and 10 = all of the time [excellent])

- | | | | | | | | | | | | | | |
|-----------------------------------------------------------|------------------|---|---|---|---|---|---|---|---|---|---|----|-----------------|
| 1. Able to breathe easily | None of the time | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | All of the time |
| 2. Been able to enjoy food | None of the time | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | All of the time |
| 3. Feeling rested | None of the time | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | All of the time |
| 4. Have had a good sleep | None of the time | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | All of the time |
| 5. Able to look after personal toilet and hygiene unaided | None of the time | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | All of the time |
| 6. Able to communicate with family or friends | None of the time | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | All of the time |
| 7. Getting support from hospital doctors and nurses | None of the time | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | All of the time |
| 8. Able to return to work or usual home activities | None of the time | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | All of the time |
| 9. Feeling comfortable and in control | None of the time | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | All of the time |
| 10. Having a feeling of general well-being | None of the time | 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | All of the time |

PART B

Have you had any of the following in the last 24 hours?

(10 to 0, where: 10 = none of the time [excellent] and 0 = all of the time [poor])

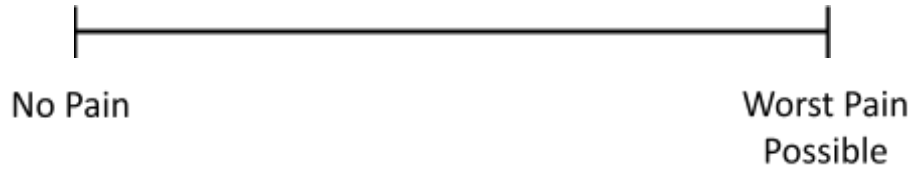
- | | | | | | | | | | | | | | |
|--------------------------------|------------------|----|---|---|---|---|---|---|---|---|---|---|-----------------|
| 11. Moderate pain | None of the time | 10 | 9 | 8 | 7 | 6 | 5 | 4 | 3 | 2 | 1 | 0 | All of the time |
| 12. Severe pain | None of the time | 10 | 9 | 8 | 7 | 6 | 5 | 4 | 3 | 2 | 1 | 0 | All of the time |
| 13. Nausea or vomiting | None of the time | 10 | 9 | 8 | 7 | 6 | 5 | 4 | 3 | 2 | 1 | 0 | All of the time |
| 14. Feeling worried or anxious | None of the time | 10 | 9 | 8 | 7 | 6 | 5 | 4 | 3 | 2 | 1 | 0 | All of the time |
| 15. Feeling sad or depressed | None of the time | 10 | 9 | 8 | 7 | 6 | 5 | 4 | 3 | 2 | 1 | 0 | All of the time |

QoR-15 total score: /150

VAS Pain Scores - Days Post-Op

Post-Op Day 1

Morning:



VAS Pain (mm): _____

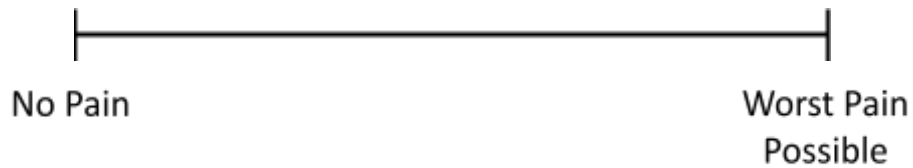
Evening:



VAS Pain (mm): _____

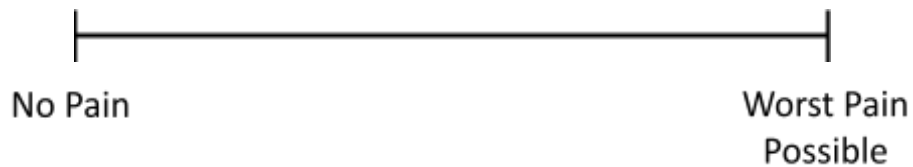
Post-Op Day 2

Morning



VAS Pain (mm): _____

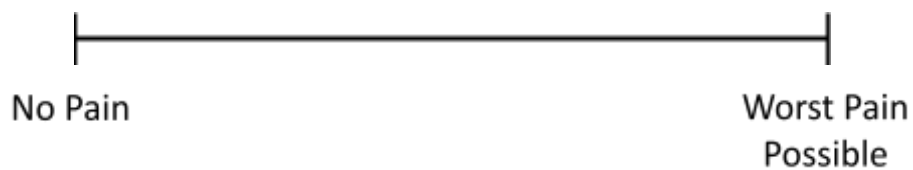
Evening



VAS Pain (mm): _____

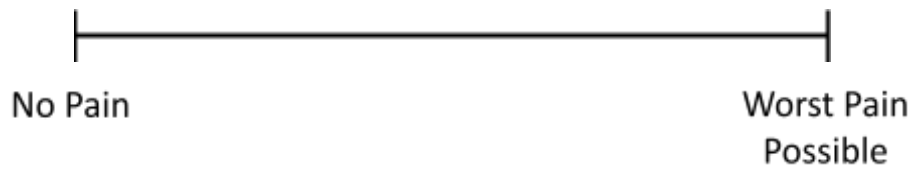
Post-Op Day 3

Morning



VAS Pain (mm): _____

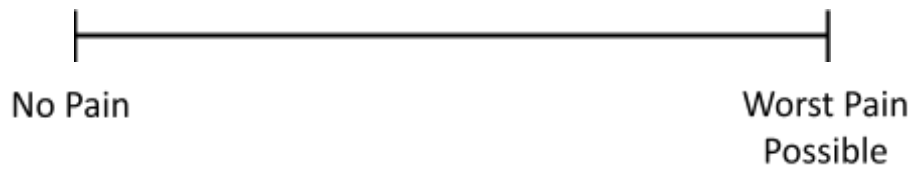
Evening



VAS Pain (mm): _____

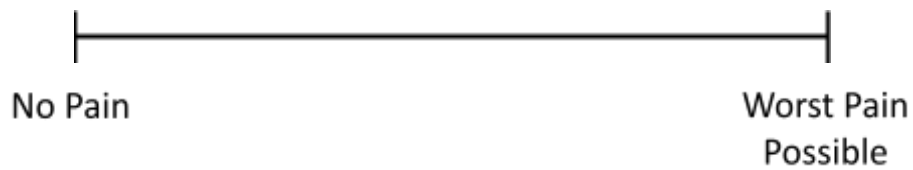
Post-Op Day 4

Morning



VAS Pain (mm): _____

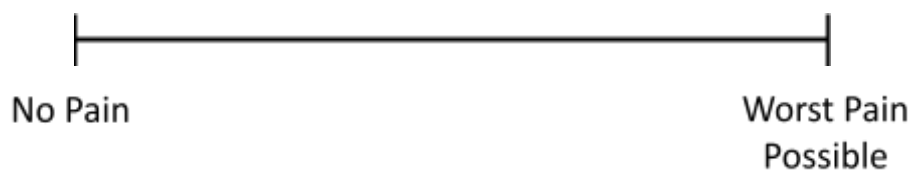
Evening



VAS Pain (mm): _____

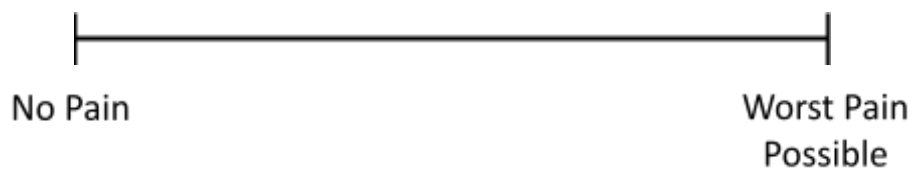
Post-Op Day 5

Morning



VAS Pain (mm): _____

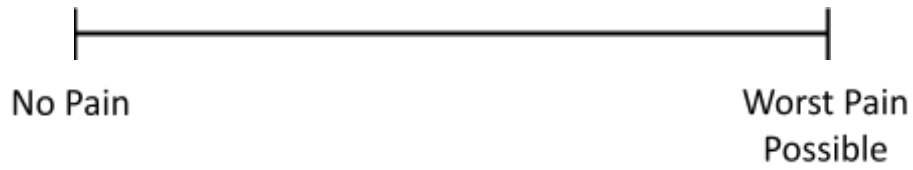
Evening



VAS Pain (mm): _____

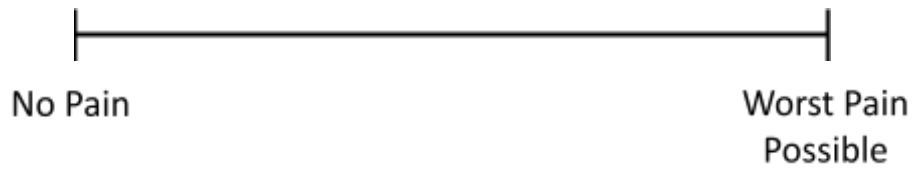
Post-Op Day 6

Morning



VAS Pain (mm): _____

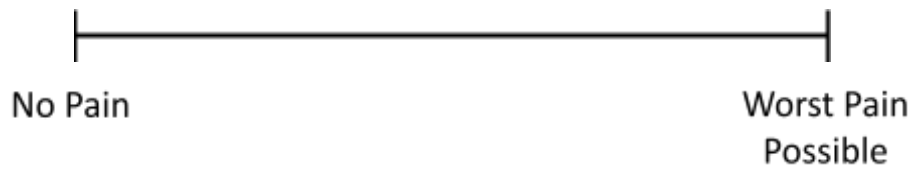
Evening



VAS Pain (mm): _____

Post-Op Day 7

Morning



VAS Pain (mm): _____

Evening



VAS Pain (mm): _____

Table 2 - VAS Pain Days Post-Op

Post-Op Day:	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Morning (8am)							
Evening (5pm)							

Daily Opioid Pain Medication Used

Record in the tables below the amount of additional voluntary opioid (morphine-like) pain medication you have used per day. (N.B. Post-Op Day 0 = the day of your operation, following its completion). You may write out what you have taken as you go throughout the day, if that makes it easier e.g. every time you have one 5mg Sevredol tablet, record in the table 1x 5mg Sevredol tablet.

Table 3A - Daily Total Opioid Use (mg)

Post-Op Day:	Day 0	Day 1	Day 2	Day 3
Total Amount of Opioid Medication Used (mg)				

Table 3B - Daily Total Opioid Use (mg)

Post-Op Day:	Day 4	Day 5	Day 6	Day 7
Total Amount of Opioid Medication Used (mg)				

For Researcher use:

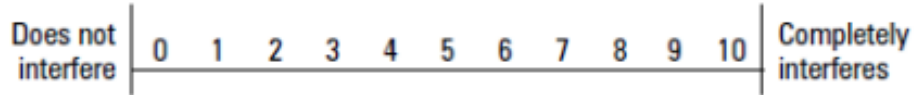
Table 4 - Daily Converted MME

Post-op Day	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
Converted MME								

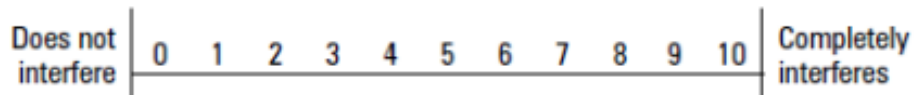
Numerical Rating Scale for Effect of Pain on Walking Ability and Sleep

Post-Op Day 1

Walking Ability (Gait):

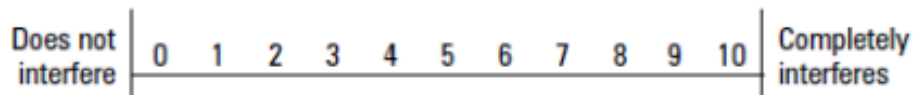


Sleep:

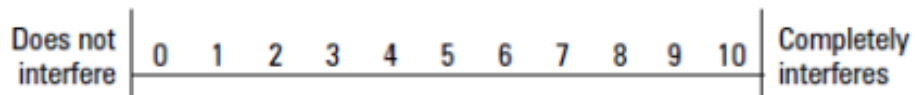


Post-Op Day 2

Walking Ability:

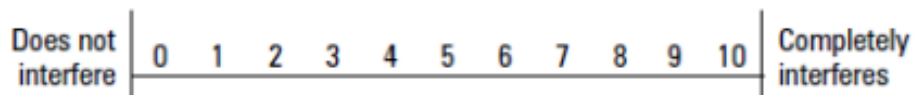


Sleep:

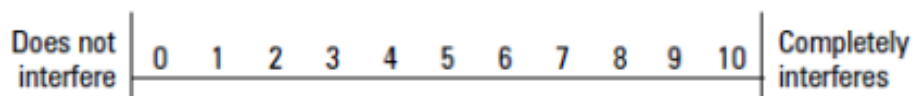


Post-Op Day 3

Walking Ability (Gait):

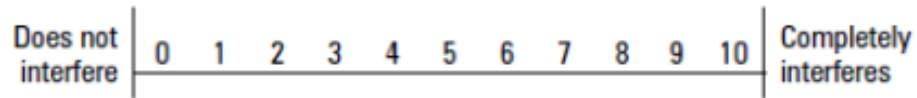


Sleep:

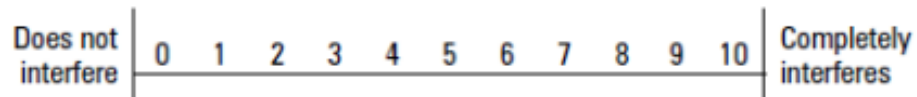


Post-Op Day 4

Walking Ability (Gait):

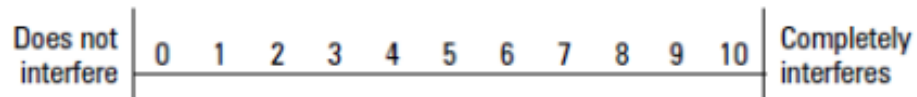


Sleep:

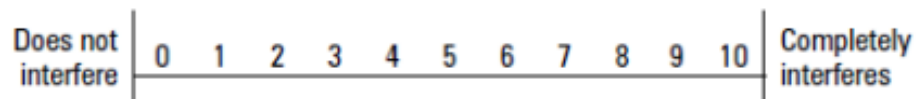


Post-Op Day 5

Walking Ability (Gait):

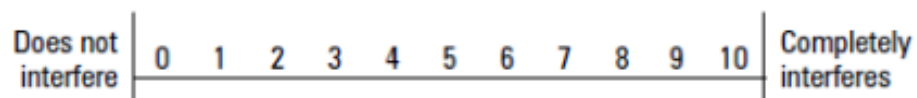


Sleep:

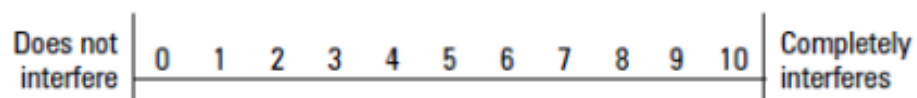


Post-Op Day 6

Walking Ability (Gait):

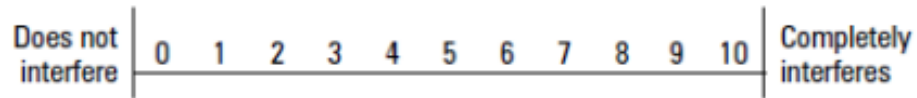


Sleep:



Post-Op Day 7

Walking Ability (Gait):



Sleep:

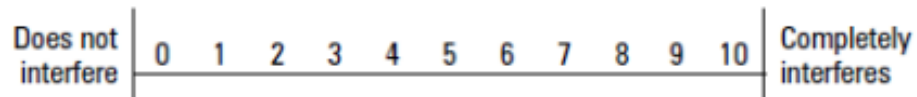
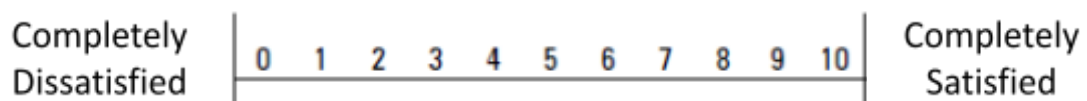


Table 5 - Daily NRS for the Effect of Pain on Walking Ability (Gait) and Sleep

Post-op Day	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7
NRS Gait							
NRS Sleep							

Numerical Rating Scale for Patient Satisfaction of their Knee Replacement

2 Week Post-Op Clinic



6 Week Post-Op Clinic

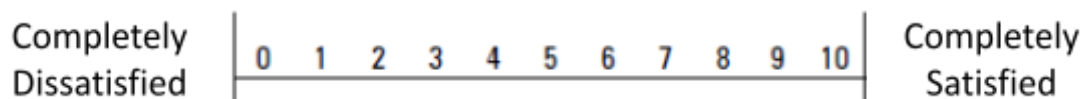


Table 6 - NRS for Patient Satisfaction

Post-op Clinic:	2 Week	6 Week
NRS Satisfaction		

