A PHASE 4, PROSPECTIVE, RANDOMIZED TRIAL TO EVALUATE POSTOPERATIVE OUTCOMES IN TOTAL KNEE ARTHROPLASTY PATIENTS USING THE DJO X4 BRACE WITH THE MOTION INTELLIGENCE PLATFORM

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STATEMENT OF COMPLIANCE

The trial will be carried out in accordance with International Conference on Harmonisation Good Clinical Practice (ICH GCP) and the following:

- United States (US) Code of Federal Regulations (CFR) applicable to clinical studies (45 CFR Part 46, 21 CFR Part 50, 21 CFR Part 56, 21 CFR Part 312, and/or 21 CFR Part 812)

The protocol, informed consent form(s), recruitment materials, and all participant materials will be submitted to the Institutional Review Board (IRB) for review and approval. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. In addition, all changes to the consent form will be IRB-approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

1 PROTOCOL SUMMARY

1.1 SYNOPSIS

Title: A phase 4, prospective, randomized trial to evaluate postoperative outcomes in total knee arthroplasty (TKA) patients using the DJO X4 brace with the Motion Intelligence Platform

Study Description:

This is a single center, investigator initiated clinical trial using a FDA approved, marketed brace called DJO X4. This phase 4, prospective, randomized clinical trial is being conducted to evaluate the use of the X4 knee brace with the Motion Intelligence platform in patients having unilateral TKA. The study is designed to determine if using a "virtual rehabilitation" device leads to enhanced recovery following TKA by improving patient objective and subjective outcome measures. These primary outcomes will be collected using a validated tool called the Knee Society Score (KSS) (Appendix A).

Patients will be randomized to one to 4 cohorts:

- Cohort 1- Study group-Home discharge. Patients randomized to this group will be provided with the X4 brace and trained on the use of Motion Intelligence platform.
- Cohort 2- Control group-Home discharge. Patients randomized to this group will serve as the control group. There will be no changes to the standard of care recovery for a TKA patient.
- Cohort 3- Study group-Inpatient rehabilitation. Patients randomized to this group will be provided with the X4 brace and trained on the use of Motion Intelligence platform.

- Cohort 4- Control group-Inpatient rehabilitation. Patients randomized to this group will serve as the control group. There will be no changes to the standard of care recovery for a TKA patient.

The aim of this study is to determine if using the X4 brace with the Motion Intelligence platform will provide enhanced, cost-effective postoperative recovery following total knee arthroplasty

Objectives:

Objectives-Primary: Efficacy

- To determine if patient postoperative outcomes, measured by the Knee Society Score, are improved by using the X4 brace with the Motion Intelligence platform

Objectives-Primary: Safety

- To monitor the patient for any device related adverse events

Objectives-Secondary: Efficacy

- To determine if there is a reduction in the rehabilitation costs (inpatient or outpatient) by using the X4 brace with the Motion Intelligence platform
- To evaluate patients satisfaction with the X4 brace with the Motion Intelligence platform
- To evaluate patients compliance and adherence using the X4 brace with the Motion Intelligence platform
- To evaluate provider satisfaction using the X4 brace with the Motion Intelligence platform

Endpoints:

Endpoints-Primary: Efficacy

- To compare the Knee Society Scores, both objective and subjective scores, done preoperatively and at 8 weeks postoperatively between the control and study groups

Endpoints-Primary: Safety

- To monitor the patient for any device related adverse events

Endpoints -Secondary: Efficacy

- To compare the number of inpatient days in a rehabilitation center between the control and study groups
- To compare the number of outpatient visits to a physical therapy center between the control and study groups
- To evaluate patients satisfaction with the X4 brace with the Motion Intelligence platform via the “System Usability Scale” (SUS) questionnaire (study group only)

	• To measure patient's compliance using the X4 brace with the Motion Intelligence platform by counting how many days they used the platform as prescribed within an 8 week period. A patient will be considered compliant if they use the platform once a day. • To measure patient's adherence using the X4 brace with the Motion Intelligence platform. Adherence is defined as performing the entire exercise routine as prescribed once a day. • To evaluate provider satisfaction with the X4 brace with the Motion Intelligence platform via the "System Usability Scale" (SUS) questionnaire (study group only)
Study Population:	240 female and male patients who have had unilateral total knee arthroplasty by Drs. Krauss or Segal
Phase:	4
Description of Sites/Facilities Enrolling Participants:	Department of Orthopaedics, Syosset Hospital
Description of Study Intervention:	The X4 brace with the Motion Intelligence platform is intended to supplement the postoperative rehabilitation process for total knee arthroplasty (TKA). This "Virtual Rehabilitation" has the advantage of guiding the patient with their prescribed exercise regimen. Additionally, as this data is available to the surgical team on a daily basis this will allow the surgical team to intervene quickly when issues are identified.
Study Duration:	The study is expected to take 1.5 years to complete
Participant Duration:	Consent for participation in the clinical trial will be obtained at any time during the preoperative period. Patients will be in the study until they have completed their 8 week postoperative surgical office visit.

1.2 SCHEME

Preoperative Period — Consent

- Total n=240
- Obtain informed consent
- Screen potential participants by inclusion and exclusion criteria
- Obtain history, document

Postopertive Day 1 to Discharge — Randomization

- Intervention Group 1 (n=120) Patient educated on the use of the X4 brace with the Motion Intelligence Platform
- Control (n=120) No intervention. Standard of care postopertive treatment regime

Postopertive Day 1 to Discharge — Study Assessments

- **Section 1.3, Schedule of Activities**

Discharge to Postopertive day 14

- **Section 1.3, Schedule of Activities**

Postoperative Day 15-56 — Study Assessments

- **Section 1.3, Schedule of Activities**

1.3 SCHEDULE OF ACTIVITIES (SOA)

This study does not require any study related screening procedures or diagnostic testing.

Schedule of Activities:

Visit Window	Pre-op	POD 1-Discharge	Discharge to Postoperative Day 14	Postoperative Day 15-56	Unscheduled postoperative visit
Consent	X				
Confirm Inclusion/Exclusion		X			
Randomization		X			
Patient Education on device/platform (if applicable)		X			
Postoperative Visits (SOC)			X (Day 14)*	X(Day 56)*	As applicable
KSS (SOC)	X			X*	
Daily Patient Log			X		
Daily exercise program as per X4 platform (study arm only)			X		
Range of Motion measured twice daily on X4 platform (study arm only)			X		
Patient Pain measured twice daily on X4 platform (study arm only)			X		
System Usability Scale" (SUS) questionnaire (study arm only)				X	

SOC=Standard of Care KSS=Knee Society Score

*Closest visit to this time point

2 INTRODUCTION

2.1 STUDY RATIONALE

Total Knee Arthroplasty (TKA) has become a rapid recovery surgery. Hospital stays are shorter with rehabilitation done either in an acute (AR), sub-acute (SAR) rehabilitation center, or at home. Therefore, the surgeon and the surgical team are only apprised of the patients' progress during routine postoperative office visits done at 2 and 8 weeks. This could potentially result in a delay of treatment for any complications related to surgery.

Following discharge from the hospital approximately 41% of TKA patients are transferred to an AR or SAR for further rehabilitation. The length of stay in these facilities varies greatly. The use of a monitoring device would allow the surgical team to remotely monitor the patient criteria for a safe discharge. This criteria includes ambulation of 150 feet, ability to climb stairs and the bending of the knee to 110 degrees. Therefore, the X4 brace could alert the surgical team of patients who are failing to progress as expected.

Home based programs require the patient perform prescribed exercise regimens twice a day. One regimen is done with the guidance of a physical therapist (PT). The second therapy is done by the patient without supervision. Though home based exercises are convenient, assuring patient compliance with these prescribed exercise regimens is unknown. Transition to an outpatient rehabilitation puts an added burden on the patient as most will require someone to drive them. Outpatient rehabilitation is 3 times per week leaving the remainder of the exercises up to the patient.

Patients and their care team need a solution to ensure both the compliance and accuracy with the exercise regimen. Currently, there is no method for the surgical team to ensure patients are following the protocols and progressing as expected. The surgical team needs a solution which would provide them more timely access to patient recovery status, activity and level of compliance. Additionally, the use of this device could also provide needed security for a patient as they are aware their surgical team is monitoring their recovery.

2.2 BACKGROUND

The X4 Knee brace with the Motion Intelligence platform is unique as it uses both a bio-measurement equipment with an interactive application thereby providing the patient with immediate feedback on their exercise regime. The Motion Intelligence platform is comprised of a portable, battery operated, microprocessor-controlled, non-invasive patient monitoring device, sensor, and a companion mobile application. The X4 Knee brace is a postoperative brace worn by a patient to monitor compliance to prescribed protocol based on the movement and function of the knee joint. Contained within the X4 Knee brace is the Mi360 sensor, which collects data autonomously, tracking steps, activity, and range of motion of the knee. The device also connects wirelessly to a companion mobile application, Motion Intelligence, and streams both real-time and collected data for review and record collection. Prescribed exercises are uploaded into the patient application, with a number of the exercises actively tracked by the Mi360 sensor housed in the X4 brace. Compliance can be tracked by the physician in real-time between postoperative visits and any medical staff on a separate dashboard.

Range of motion in flexion and extension is measured twice daily within the patient application using the Mi360 sensor housed in the X4 brace. This information is then graphically presented on the home screen in the patient application over time. Range of motion can be tracked in real-time between postoperative visits by the physician and any medical staff on a separate dashboard.

Patient pain is measured twice daily within the patient application using a visual analog scale (0-10). Patients are familiar with the visual analog scale as this scale is used during their postoperative recovery in the hospital. Patient pain can be tracked in real-time by the physician and any medical staff on a

separate dashboard. A physician dashboard is accessible to the surgical team to enable remote monitoring of patients. A summary of all patient data is made available via a web portal to the surgical team.

In order for virtual rehabilitation systems to become part of the postoperative regimen they must demonstrate feasibility, user-friendliness, high patient and clinician satisfaction, clinical efficacy, and an acceptable overall cost of care. [1]

The aim of this study is to determine if using the X4 brace with the Motion Intelligence platform will provide enhanced, cost-effective postoperative recovery following total knee arthroplasty.

2.3 RISK/BENEFIT ASSESSMENT

2.3.1 KNOWN POTENTIAL RISKS

Participation in this study does not create any additional risk for the postoperative TKA patient. The brace is designed not to impede ambulation or range of motion. The brace is adjustable to ensure patient comfort.

The X4 application will collect personal information the subjects provide, such as their name, username, password, and other identifying personal information they provide when registering with the application. Therefore, there is a potential risk of breach of confidentiality.

2.3.2 KNOWN POTENTIAL BENEFITS

The X4 brace Motion Intelligence Platform is monitored remotely by the surgical team. This remote monitoring could lead to earlier identification and intervention of postoperative issues for patients randomized to the study group.

Participating in this clinical study will contribute to current medical knowledge of these devices. The results of this study can make a difference in the care of future patients by providing information about the benefits of these interventions.

2.3.3 ASSESSMENT OF POTENTIAL RISKS AND BENEFITS

There are no anticipated problems associated with participation in this study.

3 OBJECTIVES AND ENDPOINTS

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
Primary		
• To determine if patient postoperative outcomes, measured by the Knee Society Score, are improved by using the X4 brace with the Motion Intelligence platform • To monitor the study group for any device related adverse events	• To compare the Knee Society Scores, both objective and subjective scores, done preoperatively and at 8 weeks postoperatively between the control and study groups • To monitor the study group for any device related adverse events	The Knee Society Score is a validated tool used for assessing outcome in total arthroplasty patients Patients will be followed to ensure there are no issues with the utilization of the X4 brace
Secondary		
• To determine if there is a reduction in the rehabilitation costs (inpatient or outpatient) by using the X4 brace with the Motion Intelligence platform • To evaluate patients satisfaction with the X4 brace with the Motion Intelligence platform • To evaluate patients compliance and adherence using the X4 brace with the Motion Intelligence platform	• To compare the number of inpatient days in a rehabilitation center between the control and study groups • To compare the number of outpatient visits to a physical therapy center between the control and study groups • To evaluate patient's satisfaction with the X4 brace with the Motion Intelligence platform via the "System Usability Scale" (SUS) questionnaire (study group only) • To measure patient's compliance using the X4 brace with the Motion Intelligence platform by counting how many days they used the platform as prescribed within an 8 week period. A patient will be	To evaluate if the X4 brace provides user-friendly, cost-effective, enhanced patient recovery following total knee arthroplasty

OBJECTIVES	ENDPOINTS	JUSTIFICATION FOR ENDPOINTS
	considered compliant if they use the platform once a day. • To measure patient's adherence using the X4 brace with the Motion Intelligence platform. Adherence is defined as performing the entire exercise routine as prescribed once a day.	
• To evaluate provider satisfaction using the X4 brace with the Motion Intelligence platform	• To evaluate provider satisfaction with the X4 brace with the Motion Intelligence platform via the "System Usability Scale" (SUS) questionnaire (study group only)	In order for this technology to become part a postoperative regime the platform should be both effective and user friendly for the provider

4 STUDY DESIGN

4.1 OVERALL DESIGN

Hypotheses: The X4 brace with the Motion Intelligence platform will provide an enhanced, cost-effective postoperative recovery following total knee arthroplasty (TKA).

This is a prospective, randomized clinical trial to evaluate the use of the X4 knee brace with the Motion Intelligence platform in patients having unilateral TKA. This brace is a FDA approved, marketed product being used as per the manufacturer's (DJO) marketed indications. Patients will be randomized to one to 4 cohorts:

This study is designed to determine if using a "virtual rehabilitation" device leads to enhanced recovery following total knee arthroplasty by improving patient objective and subjective outcome measures. These outcomes will be collected using a validated tool called the Knee Society Score (KSS)

(Appendix A). The KSS is a standard of care tool collected for all TKA patients pre-operatively and postoperatively at the 8 week visit.

- Cohort 1- Study group-Home discharge. Patients randomized to this group will be provided with the X4 brace and trained on the use of Motion Intelligence platform.
- Cohort 2- Control group-Home discharge. Patients randomized to this group will serve as the control group. There will be no changes to the standard of care recovery for a TKA patient.
- Cohort 3- Study group-Inpatient rehabilitation. Patients randomized to this group will be provided with the X4 brace and trained on the use of Motion Intelligence platform.
- Cohort 4- Control group-Inpatient rehabilitation. Patients randomized to this group will serve as the control group. There will be no changes to the standard of care recovery for a TKA patient.

No interim analysis is planned for this study. Randomization schedule will be done by the statistician via RedCap.

The DJO X4 brace will be provided to the patient at no cost. Study visits, hospitalization, inpatient and outpatient rehabilitation costs are standard of care and will be the responsibility of the patient. There will be no payment for participation in this study.

All study patients will complete a daily "Daily Patient Log" (Appendix B) starting the day after discharge from the hospital until postoperative day (POD) 56. This log will document the patient's location:

- Rehabilitation center or
- Home physical therapy or
- Physical therapy center
- Hospital (re-admission)
- Return to work (if applicable)

4.2 SCIENTIFIC RATIONALE FOR STUDY DESIGN

Patients who are not randomized to the X4 study cohort will follow the standard of care regimen for TKA patients and will be the control group used for comparison.

4.3 JUSTIFICATION FOR DOSE

Not Applicable.

4.4 END OF STUDY DEFINITION

The End of Study will be defined as the 8 week (visit closest to this time point) postoperative visit.

5 STUDY POPULATION

5.1 INCLUSION CRITERIA

Inclusion Criteria:

1. Age ≥ 18 or < 90
2. Able to read and speak in English
3. Patients having a unilateral total knee arthroplasty by Drs. Krauss or Segal
4. Patients with a smart phone and internet able to access the Motion Intelligence Platform
5. Patient is freely able to provide consent
6. Patients willing to comply with the standard of care postoperative visit schedule (2 and 8 weeks)
7. Agree to complete the KSS 2013 version preoperatively and at the 8 week postoperative visit (standard of care)
8. Agree to complete the study required validated System Usability Scale at the 8 week postoperative visit (Appendix C)

5.2 EXCLUSION CRITERIA

Exclusion Criteria:

1. Surgery covered by workman's compensation
2. Physical impairments which in the opinion of the surgeon will effect or limit rehabilitation (e.g.: Multiple Sclerosis, Parkinson's disease)
3. Limited mobility preoperatively requiring the use of a wheelchair
4. Chronic opioid use prior to surgery
5. Alcohol abuse
6. Participation in another clinical trial
7. Cognitive limitations which will interfere with the understanding of the Motion Intelligence platform
8. Requirement for a knee immobilizer postoperatively

5.3 LIFESTYLE CONSIDERATIONS

There are no lifestyle modifications or requirements for this study.

5.4 SCREEN FAILURES

Screen failures are defined as participants who consent to participate in the clinical trial but are not subsequently randomly assigned to the study intervention. A minimal set of screen failure information is required to ensure transparent reporting of screen failure participants, to meet the Consolidated Standards of Reporting Trials (CONSORT) publishing requirements and to respond to queries from regulatory authorities. Minimal information includes demography, screen failure details, and eligibility criteria.

5.5 STRATEGIES FOR RECRUITMENT AND RETENTION

Participation in the clinical trial will be discussed with the patient by Dr. Krauss, Dr. Segal, or a designee, when the patient is first scheduled for a unilateral total knee arthroplasty. The investigator will discuss the following:

- the purpose/objective of the study
- the study design (e.g., the number of participants)
- how patients are assigned to the treatment group
- participation in this study is not required
- patients may withdraw from this study at their discretion

The informed consent and patient product information (Appendix D) will be given to the patient to review at home. This will provide the patients with an opportunity to review the device material prior to surgery. The patients will be provided with contact information for the research staff for any questions or concerns. Consent will be obtained at any time during the preoperative period.

This study will not be including any vulnerable or cognitively impaired patients.

6 STUDY INTERVENTION

6.1 STUDY INTERVENTION(S) ADMINISTRATION

6.1.1 STUDY INTERVENTION DESCRIPTION

Patients will be consented for the study at any time during the preoperative period. Following the surgical procedure the inclusion/exclusion criteria will be confirmed. Patients meeting study inclusion/exclusion will be randomized via the REDCap system when their discharge location (home vs inpatient rehabilitation) has been confirmed. Patients randomized to the X4 brace arm of the study will be assisted with downloading the Motion Performance Platform and provided with the X4 brace during their hospital stay. The average length of stay in the hospital is 2 days. During the hospital stay the study team will work with the patient and family members to insure they are adequately trained in the use of the device and comfortable using the platform. Contact information will be provided for any issues or concerns.

PROCESS AND PATIENT ON-BOARDING

POST-OPERATIVE FOLLOWING RANDOMIZATION

Following randomization the patient will be shown how to apply brace and assisted in downloading the Motion Intelligence application from either the Apple iStore or Google Play. The patient will be assisted with pairing the device to the brace. The patient will be instructed on how to use the application and importance of using the application.

The patient will be educated to do their exercises twice a day, once in the morning and once in the afternoon. Additionally, the application screen will monitor their progress post-surgery by showing them how many steps they have taken in a day, their active time and average flexion and extension. If the patient would like to be reminded that they need to do their exercises, they can set up a reminder by going to the "Settings".

Exercise Program:

The Exercise program was developed by some Key Opinion Leaders based on common practice. The investigators have reviewed the program and are in agreement with this program. These exercises are completed throughout the 56 day program and are selected for predetermined time periods (days) after surgery (see exercise regime for details on timing):

1. Ankle Pumps / Ankle Circles
2. Isometric Quad Sets
3. Supine Heel Slides
4. Straight leg raise
5. Hamstring and Calf Stretch * Hold 10 Seconds*
6. Clamshells
7. Seated Heel Slides in Chair
8. Seated Passive Knee Extension *Hold 30 Seconds*

Each exercise has a video to show the patient how to complete the exercises. The patient starts the exercise session by selecting the first exercise. They watch the video on how to perform the exercise. Once the exercise is completed they select "Done" and move to the next exercise. The exercises must be done in order, however, if the patient cannot complete the exercise they can select "skip" and give a reason for the skip. Any exercise that bends the knee will show up on the screen when it is performed. Each period the patient has a target range of motion goal for both flexion and extension and a pain goal. The patient can see their progress while doing the exercises. Progress is based on color: with Green indicating the patient has reached the target. Yellow and Red indicate that the target has not been reached. At the end of the session the patient will be asked about their pain level and will record their highest amount of range of motion (ROM) and then they have a timer for 20 minutes of icing.

Exercise Regimen:

Postoperative Day (POD)	0-6		
Range of Motion Flexion - Target	80		
Range of Motion Extension - Target	15		
Pain - Target	7		
	Reps	**Sets**	**Time/Day**
Ankle Pumps / Ankle Circles	10	1	2
Isometric Quad Sets	10	1	2
Supine Heel Slides	10	1	2
Straight leg raise			
Hamstring and Calf Stretch * Hold 10 Seconds*			
Clamshells			
Seated Heel Slides in Chair	10	1	2
Seated Passive Knee Extension *Hold 30 Seconds*	10	1	2

Postoperative Day (POD)	7-13		
Range of Motion Flexion - Target	90		
Range of Motion Extension - Target	10		
Pain - Target	6		
	Reps	**Sets**	**Time/Day**
Ankle Pumps / Ankle Circles	10	1	2
Isometric Quad Sets	10	1	2
Supine Heel Slides	10	1	2
Straight leg raise			
Hamstring and Calf Stretch * Hold 10 Seconds*			

Clamshells			
Seated Heel Slides in Chair	10	1	2
Seated Passive Knee Extension *Hold 30 Seconds*	10	1	2

Postoperative Day (POD)	14-20		
Range of Motion Flexion - Target	100		
Range of Motion Extension - Target	5		
Pain - Target	6		
	Reps	**Sets**	**Time/Day**
Ankle Pumps / Ankle Circles	10	1	2
Isometric Quad Sets	10	1	2
Supine Heel Slides	10	1	2
Straight leg raise			
Hamstring and Calf Stretch * Hold 10 Seconds*			
Clamshells			
Seated Heel Slides in Chair	10	1	2
Seated Passive Knee Extension *Hold 30 Seconds*	10	1	2

Postoperative Day (POD)	21-27		
Range of Motion Flexion - Target	105		
Range of Motion Extension - Target	0		
Pain - Target	5		
	Reps	**Sets**	**Time/Day**
Ankle Pumps / Ankle Circles			
Isometric Quad Sets			
Supine Heel Slides			
Straight leg raise	10	1	2
Hamstring and Calf Stretch * Hold 10 Seconds*			
Clamshells	10	1	2
Seated Heel Slides in Chair	10	1	2
Seated Passive Knee Extension *Hold 30 Seconds*	10	1	2

Postoperative Day (POD)	28-34		
Range of Motion Flexion - Target	110		
Range of Motion Extension - Target	0		
Pain - Target	5		
	Reps	**Sets**	**Time/Day**
Ankle Pumps / Ankle Circles			
Isometric Quad Sets			
Supine Heel Slides			
Straight leg raise	10	1	2
Hamstring and Calf Stretch * Hold 10 Seconds*			
Clamshells	10	1	2
Seated Heel Slides in Chair	10	1	2
Seated Passive Knee Extension *Hold 30 Seconds*	10	1	2

Postoperative Day (POD)	35-41		
Range of Motion Flexion - Target	110		
Range of Motion Extension - Target	0		
Pain - Target	4		
	Reps	**Sets**	**Time/Day**
Ankle Pumps / Ankle Circles			
Isometric Quad Sets			
Supine Heel Slides			
Straight leg raise	10	1	2
Hamstring and Calf Stretch * Hold 10 Seconds*			
Clamshells	10	1	2
Seated Heel Slides in Chair	10	1	2
Seated Passive Knee Extension *Hold 30 Seconds*	10	1	2

Postoperative Day (POD)	42-48		
Range of Motion Flexion - Target	115		
Range of Motion Extension - Target	0		
Pain - Target	3		
	Reps	**Sets**	**Time/Day**
Ankle Pumps / Ankle Circles			
Isometric Quad Sets	10	1	2
Supine Heel Slides	10	1	2
Straight leg raise	10	1	2
Hamstring and Calf Stretch * Hold 10 Seconds*			

Clamshells	10	1	2
Seated Heel Slides in Chair			
Seated Passive Knee Extension *Hold 30 Seconds*			

Postoperative Day (POD)	49-55		
Range of Motion Flexion - Target	115		
Range of Motion Extension - Target	0		
Pain - Target	2		
	Reps	**Sets**	**Time/Day**
Ankle Pumps / Ankle Circles			
Isometric Quad Sets	10	1	2
Supine Heel Slides	10	1	2
Straight leg raise	10	1	2
Hamstring and Calf Stretch * Hold 10 Seconds*			
Clamshells	10	1	2
Seated Heel Slides in Chair			
Seated Passive Knee Extension *Hold 30 Seconds*			

Postoperative Day (POD)	56	(End of Study)	
Range of Motion Flexion - Target	120		
Range of Motion Extension - Target	0		
Pain - Target	2		
	Reps	**Sets**	**Time/Day**
Ankle Pumps / Ankle Circles			
Isometric Quad Sets	10	1	2
Supine Heel Slides	10	1	2

Straight leg raise	10	1	2
Hamstring and Calf Stretch * Hold 10 Seconds*			
Clamshells	10	1	2
Seated Heel Slides in Chair			
Seated Passive Knee Extension *Hold 30 Seconds*			

Monitoring the patient

The Motion Intelligence application allows the patient to send messages to their care team and allows the patient to send pictures of their knee if needed. Additionally there is product support for the patient. This support from DJO is available by phone and email:

- Email support at *Misupport@djoglobal.com*
- Email at *support@motionmd.com*
- Phone (844)273-0200

6.1.2 DOSING AND ADMINISTRATION

Not Applicable

6.2 PREPARATION/HANDLING/STORAGE/ACCOUNTABILITY

6.2.1 ACQUISITION AND ACCOUNTABILITY

Not Applicable

6.2.2 FORMULATION, APPEARANCE, PACKAGING, AND LABELING

Not Applicable

6.2.3 PRODUCT STORAGE AND STABILITY

Not Applicable

6.2.4 PREPARATION

Not Applicable

6.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

Randomization:

Prior to randomization, patients will be stratified according to discharge location (home, inpatient rehabilitation). Within each stratum, patients will be randomly assigned in a 1:1 ratio to the X4 brace with the Motion Intelligence platform or standard of care.

The Biostatistics Unit will develop a randomization procedure using a permuted block design within the REDCap system). Additional details of the procedure, including required record keeping, will be further developed upon approval of this protocol. The Biostatistics Unit has extensive experience in implementing and in producing detailed documentation for such procedures.

Blinding and Concealed Allocation

Due to the nature of the X4 brace, it is not possible to blind the investigators or the participants. The randomization assignment will be obtained from BRMS, after consent has been obtained, after it has been determined that the subject has met all inclusion/exclusion criteria, and after the discharge location has been determined.

6.4 STUDY INTERVENTION COMPLIANCE

Patients randomized to the X4 brace cohort are required to access the system twice daily. Patients who have not accessed the system for over 72 hours will be contacted to determine the reason for non-compliance.

Compliance and adherence with the X4 brace with the Motion Intelligence platform are secondary outcomes of this study.

6.5 CONCOMITANT THERAPY

Not Applicable

6.5.1 RESCUE MEDICINE

Not Applicable

7 STUDY INTERVENTION DISCONTINUATION AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 DISCONTINUATION OF STUDY INTERVENTION

Patients may discontinue using the X4 brace, however, this does not mean discontinuation from the study. The brace is single use and patients will not be required to return the brace.

7.2 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from participation in the study at any time upon request. All analyses will be carried out according the ITT principle. The ITT population will be all patients randomized, regardless of whether or not treatment was administered. All patients will be analyzed in the group to which they were randomized.

An investigator may discontinue or withdraw a participant from the study for the following reasons:

- Significant study intervention non-compliance
- A medical condition or situation occurs such that continued participation in the study would not be in the best interest of the participant

The reason for participant discontinuation or withdrawal from the study will be recorded in REDCap.

7.3 LOST TO FOLLOW-UP

A participant will be considered lost to follow-up if he or she fails to return for the 8 week postoperative visit and is unable to be contacted by the study site staff.

The site will attempt to contact the participant and reschedule the missed visit as soon as possible and counsel the participant on the importance of maintaining the assigned visit schedule and ascertain if the participant wishes to and/or should continue in the study. Before a participant is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the participant (where possible, 3 telephone calls and, if necessary, a certified letter to the participant's last known mailing address or local equivalent methods). These contact attempts should be documented in the participant's medical record or study file. Should the participant continue to be unreachable, he or she will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

8 STUDY ASSESSMENTS AND PROCEDURES

8.1 EFFICACY ASSESSMENTS

Study Cohort Patients Only (Patients randomized to the X4 brace with the Motion Intelligence platform):

Patients will follow the prescribed exercises available on the patient application, with a number of the exercises actively tracked by the Mi360 sensor housed in the X4 brace. Compliance will be monitored by the physician and/or a delegated medical professional between postoperative visits on the Motion Intelligence dashboard.

Range of motion in flexion and extension will be measured twice daily within the patient application using the Mi360 sensor housed in the X4 brace. This information is then graphically presented on the home screen in the patient application over time. Range of motion can be tracked in real-time between postoperative visits by the physician and/or a delegated medical professional between postoperative visits on the Motion Intelligence dashboard.

Patient's will be required to access the application twice daily to enter their pain scores using the visual analog scale (0-10). Patient pain can be tracked in real-time by the physician and/or a delegated medical professional between postoperative visits on the Motion Intelligence dashboard.

All study patients:

All study patients will complete a daily "Daily Patient Log" starting the day after discharge from the hospital until postoperative day (POD) 56. This log will document the patient's location:

- Rehabilitation center or
- Home physical therapy or
- Physical therapy center
- Hospital (readmission)
- Return to work (if applicable)

All study patients will be required to complete a preoperative and 8 week postoperative Knee Society Score questionnaire. This questionnaire is a standard of care for all total knee arthroplasty patients having surgery by Drs. Krauss and Segal.

8.2 SAFETY AND OTHER ASSESSMENTS

This clinical trial does not require any study specific screening tests or procedures. Preoperative screening done as part of the standard of care for a preoperative arthroplasty patient will be used to determine patient inclusion and exclusion. Additionally, there are no required on study lab testing or procedures required.

8.3 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS

8.3.1 DEFINITION OF ADVERSE EVENTS (AE)

Medical Device Reporting:

This clinical trial is evaluating a commercially available marketed medical device (X4 brace). The device is being used according to the manufacture's guidelines.

This study will adhere to the adverse event reporting regulations of the Centers for Devices and Radiological Health (CDRH), part of the Food and Drug Administration (FDA) regulations. In accordance with the Safe Medical Devices Act of 1990 (SMDA) (Public Law 102-629) (21 CFR 803.32 (c)) ambulatory surgery centers, hospitals, outpatient diagnostic centers and other user facilities are required to report all incidents in which a medical device or user error may have caused or contributed to the death, serious injury or serious illness of a patient.

Adverse Event Reporting Period

The study period during which adverse events must be reported is defined as the period from the initiation of any study procedures to the end of the study treatment follow-up. For this study, the initiation of study procedure will be from when the study subject starts using the X4 brace with the Motion Intelligence platform through the 8 week postoperative visit.

8.3.2 DEFINITION OF SERIOUS ADVERSE EVENTS (SAE)

Device User Facility Reporting Requirements of Serious Adverse Events:

A "device user facility" is a hospital, ambulatory surgical facility, nursing home, outpatient diagnostic facility, or outpatient treatment facility, which is not a physician's office. All deaths and serious injuries to which the device has or may have caused or contributed will be reported to the IRB, FDA and the manufacturer. The user facility will also submit annual reports to the FDA by January 1 of each year as described in 21 CFR 803.33.

Form 3419 Annual User Facility Report

- Medical Device Reporting Annual User Facility Report - Form FDA3419
- Instructions for Completing the Medical Device Reporting Annual User Facility Report, Form FDA3419

Serious Injury or illness definition:

"Serious injury or illness" means those injuries that are life threatening, result in permanent body function impairment or permanent damage to a body structure, or necessitate immediate medical or

surgical intervention to prevent permanent body function impairment or permanent damage to a body structure (21 CFR 803.3) (r).

A device may have "caused or contributed to" a patient's death or serious injury, if the death or serious injury was or may have been attributed to the device or the device may have been a factor in the death or serious injury because of:

- Device failure
- Malfunction
- Improper or inadequate device design
- Manufacture
- Labeling or
- User error

8.3.3 CLASSIFICATION OF AN ADVERSE EVENT

8.3.3.1 SEVERITY OF EVENT

All adverse events that do not meet any of the criteria for serious should be regarded as ***non-serious adverse events***. Any non-serious adverse event felt to be related to the study device will be captured in the source documents and case report form.

- **Mild** – Events require minimal or no treatment and do not interfere with the participant's daily activities.
- **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
- **Severe** – Events interrupt a participant's usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating. Of note, the term "severe" does not necessarily equate to "serious".

8.3.3.2 RELATIONSHIP TO STUDY INTERVENTION

All adverse events (AEs) must have their relationship to study intervention (device) assessed by the clinician who examines and evaluates the participant based on temporal relationship and his/her clinical judgment. The degree of certainty about causality will be graded using the categories below. In a clinical trial, the study product must always be suspect.

- **Related** – The AE is known to occur with the study intervention, there is a reasonable possibility that the study intervention caused the AE, or there is a temporal relationship between the study intervention and event. Reasonable possibility means that there is evidence to suggest a causal relationship between the study intervention and the AE.
- **Not Related** – There is not a reasonable possibility that the administration of the study intervention caused the event, there is no temporal relationship between the study intervention and event onset, or an alternate etiology has been established.

8.3.3.3 EXPECTEDNESS

The Principal Investigator will be responsible for determining whether an adverse event (AE) is expected or unexpected. An AE will be considered unexpected if the nature, severity, or frequency of the event is not consistent with the risk information previously described for the study intervention.

8.3.4 TIME PERIOD AND FREQUENCY FOR EVENT ASSESSMENT AND FOLLOW-UP

The occurrence of an adverse event (AE) or serious adverse event (SAE) may come to the attention of study personnel during study visits and interviews of a study participant presenting for medical care.

All AEs including local and systemic reactions not meeting the criteria for SAEs will be captured on the appropriate case report form (CRF). Information to be collected includes event description, time of onset, clinician's assessment of severity, relationship to study product (assessed only by those with the training and authority to make a diagnosis), and time of resolution/stabilization of the event. All AEs occurring while on study must be documented appropriately regardless of relationship. All AEs will be followed to adequate resolution.

Changes in the severity of an AE will be documented to allow an assessment of the duration of the event at each level of severity to be performed. AEs characterized as intermittent require documentation of onset and duration of each episode.

At each study visit, the investigator will inquire about the occurrence of AE/SAEs since the last visit. Events will be followed for outcome information until resolution or stabilization.

8.3.5 ADVERSE EVENT REPORTING

This clinical trial consists of postoperative total knee arthroplasty patients. DRE's common and expected in this group of patients include postoperative pain, nausea, hypotension, anemia, and dehydration. Events anticipated and expected in the postoperative arthroplasty patient will not be considered an adverse event for collection in the eCRF. Additionally, there are no study interventions for the control group. This group will be following the standard of care treatment for a total knee arthroplasty patient. Therefore, no adverse events related to the study will be occurring in this group.

8.3.6 SERIOUS ADVERSE EVENT REPORTING

The study investigator shall complete an Unanticipated Adverse Device Effect Form and submit to the reviewing Institutional Review Board (IRB) as soon as possible, but in no event later than 10 working

days after the investigator first learns of the effect. The investigator is responsible for conducting an evaluation of an unanticipated adverse device effect and shall report the results of such evaluation to the Food and Drug Administration (FDA). Thereafter, the investigator shall submit such additional reports concerning the effect as FDA requests.

8.3.7 REPORTING EVENTS TO PARTICIPANTS

Not Applicable

8.3.8 EVENTS OF SPECIAL INTEREST

Not Applicable

8.3.9 REPORTING OF PREGNANCY

Not Applicable

8.4 UNANTICIPATED PROBLEMS

8.4.1 DEFINITION OF UNANTICIPATED PROBLEMS (UP)

Not Applicable

8.4.2 UNANTICIPATED PROBLEM REPORTING

Not Applicable

8.4.3 REPORTING UNANTICIPATED PROBLEMS TO PARTICIPANTS

Not Applicable

9 STATISTICAL CONSIDERATIONS

9.1 STATISTICAL HYPOTHESES

- Primary Efficacy Endpoint(s):

Knee Society Scores will be obtained prior to surgery, and at 8 weeks postoperatively
- Objective knee score (completed by the surgeon)
- Subjective knee score (completed by patient)

- Secondary Efficacy Endpoint(s):

All outcomes will be measured at 8 week postoperative visit or the visit closest to this time point

Outcomes for all patients regardless of discharge location
- Number of outpatient visits to a physical therapy center

Outcomes for patients discharged to inpatient rehabilitation
- Number of inpatient days in a rehabilitation center

Outcomes for patients randomized to the X4 brace with the Motion Intelligence platform
- Patient satisfaction with the X4 brace with the Motion Intelligence platform: Patients will complete the System Usability Scale (SUS)
- Compliance in using the X4 brace with the Motion Intelligence platform: Patients will be instructed to use the X4 brace twice a day. For each day, a subject will be considered compliant if they access the platform at least once a day, and non-compliant if they do not access at all the platform that day.
- Adherence using the X4 brace with the Motion Intelligence platform: For each day, a subject will be considered adherent if they perform the entire exercise routine as prescribed at least once a day, and non-adherent if they do not perform the entire exercise routine that day.

- Primary Safety Endpoint(s)

- Adverse Events related to the X4 brace will be collected in patients regardless of discharge location.

9.2 SAMPLE SIZE DETERMINATION

Sample Size Justification:

Based on preliminary data (from the Total Knee Arthroplasty Registry), there were 244 patients treated under the standard of care, with a KSS subjective score obtained between 6 and 10 weeks after surgery. We will use this information to estimate the KSS subjective score for the standard of care group at 8 weeks after surgery. The mean KSS subjective score in these patients was 108.5, with a standard deviation of 27.5. We believe that a 10 point improvement is clinically meaningful. We further assume that the scores for those discharged to home, and those discharged to inpatient rehabilitation will be similar, (i.e. no interaction between intervention group and discharge location). Therefore, we will use a two sided two-sample t-test to simplify the calculation. In addition, the KSS subjective scores in our preliminary data were normally distributed, and so the calculation uses the raw (untransformed) data.

A sample size of 120 patients per group will yield 80% power to detect a 10 point difference between the two intervention groups using a two sided two-sample t-test at the 0.05 significance level. As

dropout is expected to be very low, no adjustment for attrition will be made. Therefore, the total sample size will be 240 patients (120 per group).

9.3 POPULATIONS FOR ANALYSES

Intention to Treat (ITT):

All analyses will be carried out according the ITT principle. The ITT population will be all patients randomized, regardless of whether or not treatment was administered. All patients will be analyzed in the group to which they were randomized.

9.4 STATISTICAL ANALYSES

9.4.1 GENERAL APPROACH

Descriptive statistics (frequency distribution and percentage for categorical variables; mean, SD, median, interquartile range, minimum, maximum for continuous variables) of patient demographics, clinical characteristics, and medical history.

9.4.2 ANALYSIS OF THE PRIMARY EFFICACY ENDPOINT(S)

Statistical Methods:

Primary Outcomes: Efficacy

For each Knee Society Score, (objective score and subjective score), analysis of covariance (ANCOVA) will be used to examine the association between that score and intervention group (X4 brace, standard of care). The corresponding pre-op score will be included as a covariate in the model. Discharge location (home, inpatient rehabilitation) will also be included in the model. If the interaction between intervention group and discharge location is significant, then pairwise comparisons of intervention group within each discharge location will be examined within the ANCOVA model. If the usual assumptions of the ANCOVA model are not met, either a suitable transformation, or an appropriate nonparametric method will be used.

9.4.3 ANALYSIS OF THE SECONDARY ENDPOINT(S)

Secondary Outcomes: Efficacy

<u>Outcomes for all patients regardless of discharge location:</u>

The association between number of outpatient visits to a physical therapy center and intervention group will be examined using Poisson regression. Discharge location (home, inpatient rehabilitation) will also

be included in the model. If the interaction between intervention group and discharge location is significant, then pairwise comparisons of intervention group within each discharge location will be examined within the Poisson regression model. If the Poisson model does not fit the data well, alternative methods for count data will be considered.

Outcomes for patients discharged to inpatient rehabilitation:

Number of inpatient days in a rehabilitation center

The association between number of inpatient days in a rehabilitation center and intervention group will be examined using Poisson regression. If the Poisson model does not fit the data well, alternative methods for count data will be considered.

Outcomes for patients randomized to the X4 brace with the Motion Intelligence platform:

The association between patient satisfaction with the X4 brace, as measured by the SUS scale, and discharge location (home, inpatient rehabilitation) will be examined using the two sided, two sample t-test. If the usual assumptions required for the t-test are not met, either a suitable transformation, or an appropriate nonparametric method will be used.

The association between number of days of compliance and discharge location will be examined using Poisson regression. If the Poisson model does not fit the data well, alternative methods for count data will be considered.

The association between number of days of adherence and discharge location will be examined using Poisson regression. If the Poisson model does not fit the data well, alternative methods for count data will be considered.

Other outcomes:

Provider satisfaction with the X4 brace, as measured by the SUS scale will be described by calculating summary statistics (median, 25th percentile, 75th percentile, minimum and maximum).

9.4.4 SAFETY ANALYSES

Safety Outcomes:

Outcomes for patients randomized to the X4 brace regardless of discharge location

- Adverse events: Each subject will be categorized at the end of the study as having had one or more adverse events, or not having had any adverse events.
- Serious adverse events: Each subject will be categorized at the end of the study as having had one or more adverse events, or not having had any serious adverse events.

9.4.5 BASELINE DESCRIPTIVE STATISTICS

Not Applicable

9.4.6 PLANNED INTERIM ANALYSES

Not Applicable

9.4.7 SUB-GROUP ANALYSES

Not Applicable

9.4.8 TABULATION OF INDIVIDUAL PARTICIPANT DATA

Not Applicable

9.4.9 EXPLORATORY ANALYSES

Not Applicable

10 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

10.1.1 INFORMED CONSENT PROCESS

10.1.1.1 CONSENT/ASSENT AND OTHER INFORMATIONAL DOCUMENTS PROVIDED TO PARTICIPANTS

Consent forms describing in detail the study intervention, study procedures, and risks are given to the participant and written documentation of informed consent is required prior to starting study intervention.

10.1.1.2 CONSENT PROCEDURES AND DOCUMENTATION

Informed consent is a process that is initiated prior to the individual's agreeing to participate in the study and continues throughout the individual's study participation. Consent forms will be Institutional Review Board (IRB)-approved and the participant will be asked to read and review the document. The

investigator will explain the research study to the participant and answer any questions that may arise. A verbal explanation will be provided in terms suited to the participant's comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants. Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participants should have the opportunity to discuss the study with their family or surrogates or think about it prior to agreeing to participate. The participant will sign the informed consent document prior to any procedures being done specifically for the study. Participants must be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. A copy of the informed consent document will be given to the participants for their records. The informed consent process will be conducted and documented in the source document (including the date), and the form signed, before the participant undergoes any study-specific procedures. The rights and welfare of the participants will be protected by emphasizing to them that the quality of their medical care will not be adversely affected if they decline to participate in this study.

10.1.2 STUDY DISCONTINUATION AND CLOSURE

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. If the study is prematurely terminated or suspended, the Principal Investigator (PI) will promptly inform study participants and the Institutional Review Board (IRB). Study participants will be contacted, as applicable, and be informed of changes to study visit schedule.

Circumstances that may warrant termination or suspension include, but are not limited to:

- Determination of unexpected, significant, or unacceptable risk to participants
- Demonstration of efficacy that would warrant stopping
- Insufficient compliance to protocol requirements
- Data that are not sufficiently complete and/or evaluable
- Determination that the primary endpoint has been met
- Determination of futility

Study may resume once concerns about safety, protocol compliance, and data quality are addressed, and satisfy the IRB.

10.1.3 CONFIDENTIALITY AND PRIVACY

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their interventions. This confidentiality is extended to cover clinical information relating to participants. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

All research activities will be conducted in as private a setting as possible.

Representatives of the Institutional Review Board (IRB) and regulatory agencies may inspect all documents and records required to be maintained by the investigator, including but not limited to,

medical records (office, clinic, or hospital) and pharmacy records for the participants in this study. The clinical study site will permit access to such records.

The study participant's contact information will be securely stored at each clinical site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB Institutional policies.

DJO PRIVACY POLICY-Last Updated: February 2018

DJO, LLC ("DJO", "We," "Our", or "Us") takes your privacy very seriously. This privacy policy describes Our collection of Personal Data when you use Our mobile App ("App") for Our X4 knee brace ("Knee Brace"). This policy describes Our use and disclosure of such Personal Data, and the steps We take to protect such personal data. "Personal Data" means any information relating to an identified or identifiable natural person including your health information as described below. By downloading or using Our App you agree to and consent to the collection and use of your information as described below.

By accepting this Privacy Policy you expressly acknowledge that you have read and understood Our HIPAA Notice of Privacy Practices, which describes how We may use and disclose health information about you for treatment, payment or health care operations and for other purposes that are permitted or required by law, including the Health Insurance Portability and Accountability Act of 1996, as amended from time to time ("HIPAA"). Our HIPAA Notice of Privacy Practices is available at http://www.djoglobal.com/corporateinfo/compliance/hipaa. Any conflict between this Privacy Policy and the HIPAA Notice Privacy Practices with respect to any PHI (as defined in the HIPAA Notice) shall be governed by the HIPAA Notice. **If you do not want Us to use your information or your data as stated in this Privacy Policy, please do not download or use Our App.** We, with the help of Our partner, have developed the App to facilitate the collection of your postoperative knee movement data through the DJO Mi360 sensor in the Knee Brace. This will allow your health care provider to access and view the data to monitor your knee's range of motion and rehabilitation process. The App is designed for users over 18 years of age who have received access through the registration process. Your health care providers will have other policies related to the way they use and disclose information accessible to them. Please review your health care providers' Notice of Privacy Practices or any other Privacy Statement they may have.

Information We Collect

We collect the following information from you: Personal information that you provide, such as your name, username, password, and other identifying personal information you provide when registering with the App; Health Information, including identifying information related to your Knee Brace, and data from that Knee Brace related to its use, including range of motion and rehabilitation progress; The name and contact information of your health care provider; Information related to the timing of the transmission of data from your Knee Brace to the web portal accessible by your healthcare provider, and your health care provider's access of that information; and other Information such as comments or questions you have provided to us. In addition to the data listed above, We automatically collect and store: Knee Brace event information such as errors, system activity, and the dates and times of your activity; Standard log information such as how you used the App.

How We Use Information We use your contact information to contact you for administrative purposes regarding your use of the App. We use the data collected through the App to provide information to

your health care provider on your range of motion progress of your Knee Brace and other rehabilitation related data. We use the information that We collect through the App to operate, maintain, enhance, and provide all features of the App. We also use the information to provide services to respond to comments and questions for user support. Aggregated Data is information about some or all of the Users of the App, but unlike Personal Data, does not reflect or reference an individually identifiable individual. We may use Aggregated Data in research studies, for marketing purposes or other purposes in connection with Our business as permitted by applicable law. We will not access your personal contacts, other applications, or personal photos. We use standard log files and other automatically-collected usage data that is essential for the App to function effectively, including to: (i) personalize the App such as by remembering information so that it does not need to be re-entered; (ii) monitor and analyze the App; (iii) monitor aggregate App usage metrics; and (iv) track your activities on the App.

How We Disclose Information Except as described in this Privacy Policy, We will not sell, rent, lease, give away, disclose or share your contact information, and, except as described below, will not disclose your Personal Data that we collect through the App to third parties without your consent. We may provide contact or App information to third parties if you consent to Us doing so,as well as in the following circumstances: We will provide Personal Data collected through your Knee Brace (such as range of motion and rehabilitation related data) to your health care provider. Please note that your health care provider's privacy policy will determine how the health care provider protects your health information. We may provide your Personal Data to third parties who provide services on Our behalf. We take steps to limit the Personal Data provided to them to that which is reasonably necessary for them to perform their functions.

We require them by contract to agree to only process the Personal Data in accordance with Our instructions and to maintain the security and confidentiality of such information by applying adequate technical and organizational security measures. To the extent permitted by applicable law, We may disclose your Personal Data if required to do so by law to comply with state and federal laws, in response to a court order, judicial or other government subpoena or warrant, or to otherwise cooperate with law enforcement or other governmental agencies. We also reserve the right to disclose your information that We believe, in good faith, is appropriate or necessary to (i) take precautions against liability, (ii) protect ourselves or others from fraudulent, abusive, or unlawful uses or activity, (iii) investigate and defend ourselves against any third-party claims or allegations, (iv) protect the security or integrity of the App and any facilities or equipment used to make the App available, or (v) protect Our property or other legal rights (including, but not limited to, enforcement of Our agreements), or the rights, property, or safety of others. We will notify you of any such disclosures. Information about Our users, including Personal Data, may be disclosed and otherwise transferred to an acquirer, successor, or assignee as part of any merger, acquisition, debt financing, sale of assets, or similar transaction, or in the event of an insolvency, bankruptcy, or receivership in which information is transferred to one or more third parties as one of Our business assets, to the extent and in the way as prescribed by applicable law. We will combine your Personal Data with those of other App users to create Aggregated Data.

Do Not Track: We do not track Our App users over time and across third party websites or online services to provide targeted advertising, and we do not respond to Do Not Track signals.

Data Security: We use appropriate physical, managerial and technical safeguards that are designed to protect the confidentiality, integrity and security of Personal Data that We collect and maintain against accidental or unlawful loss, theft and misuse and unauthorized access, disclosure, alteration destruction, or any other type of unlawful processing. We cannot, however, fully guarantee the security of Personal Data or other information transmitted through the App. You are responsible for maintaining the

confidentiality of your App access information and password. You agree to accept responsibility for all activities that occur under your password.

Rights and Choices

You may have certain rights regarding the Personal Data we maintain about you. You may have the right to request access to receive information about the Personal Data We maintain about you, or have your Personal Data rectified, blocked, or deleted if it is incorrect, inaccurate, or outdated. Following your request, We will accommodate your request as required by applicable law. You may discontinue information collection by uninstalling the App. You may use the standard uninstall processes as may be available as part of your mobile device or via the mobile application marketplace. If you have questions about your rights and choices in relation to your Personal Data, or would like to request additional information, please contact MI360support@djoglobal.com or write to Us at: DJO Global, Attn: MI360 Support,1430 Decision Street, Vista, CA 92081.

Changes to Our Privacy Policy

We may change this Privacy Policy from time to time. Any changes will be posted on the App with an updated revision date. In the event that any changes to this Privacy Policy materially alter your rights or obligations under this Privacy Policy, We will make reasonable efforts to notify you of the change. For example, we may send a message to your email address, if we have one on file, or generate a PUSH message or similar notification when you access the App for the first time after such material changes are made. You will need access to the App or your email server for access to review and save the revised Privacy Policy. Your continued use of the App after the revised Privacy Policy has become effective indicates that you have read, understood and agreed to the then current version of this Privacy Policy.

10.1.4 FUTURE USE OF STORED SPECIMENS AND DATA

Not Applicable

10.1.5 KEY ROLES AND STUDY GOVERNANCE

Provide the name and contact information of the Principal Investigator and the Medical Monitor.

Principal Investigator	**Medical Monitor**
Eugene Krauss,MD,FAAOS,FACS	*Not Applicable*
Syosset Hospital, Northwell Health	*Institution Name*
221 Jericho Turnpike	*Address*
516-496-2637	*Phone Number*
ekrauss@northwell.edu	*Email*

Steering Committee, Executive Committee, Subcommittee are Not applicable for this study.

10.1.6 SAFETY OVERSIGHT

Not Applicable

10.1.7 CLINICAL MONITORING

Not Applicable

10.1.8 QUALITY ASSURANCE AND QUALITY CONTROL

The clinical site will perform internal quality management of study conduct, data documentation and completion. An individualized quality management plan will be developed to describe a site's quality management. The investigational site will provide direct access to all trial related sites, source data/documents, and reports for the purpose of monitoring and auditing by local and regulatory authorities.

10.1.9 DATA HANDLING AND RECORD KEEPING

10.1.9.1 DATA COLLECTION AND MANAGEMENT RESPONSIBILITIES

Data collection is the responsibility of the clinical trial staff at the site under the supervision of the site investigator. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

All source documents should be completed in a neat, legible manner to ensure accurate interpretation of data.

Hardcopies of the study visit worksheets will be provided for use as source document worksheets for recording data for each participant enrolled in the study. Data recorded in the electronic case report form (eCRF) derived from source documents should be consistent with the data recorded on the source documents.

Clinical data, including device related adverse events (AEs), data will be entered into the REDCap system. The data system includes password protection and internal quality checks, such as automatic range checks, to identify data that appear inconsistent, incomplete, or inaccurate. Clinical data will be entered directly from the source documents.

10.1.9.2 STUDY RECORDS RETENTION

Study document will be retained for 10 years following study termination.

10.1.10 PROTOCOL DEVIATIONS

A protocol deviation is any noncompliance with the clinical trial protocol, International Conference on Harmonisation Good Clinical Practice (ICH GCP), or Manual of Procedures (MOP) requirements. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

These practices are consistent with ICH GCP:

- 4.5 Compliance with Protocol, sections 4.5.1, 4.5.2, and 4.5.3
- 5.1 Quality Assurance and Quality Control, section 5.1.1
- 5.20 Noncompliance, sections 5.20.1, and 5.20.2.

Protocol deviations must be sent to the reviewing Institutional Review Board (IRB) per their policies. The site investigator is responsible for knowing and adhering to the reviewing IRB requirements. Further details about the handling of protocol deviations will be included in the MOP.

10.1.11 PUBLICATION AND DATA SHARING POLICY

Investigators intend to publish the results of this study. Any published results will only include an aggregate of de-identified data. No protected health information will be disclosed outside of Northwell Health for the purposes of this research.

10.1.12 CONFLICT OF INTEREST POLICY

Eugene Krauss and Ayal Segal, the study doctors, receives financial support from DJO Global, the company that is involved in this study. The money this study doctor receives from this company is for work as a consultant and is separate from this study. The study doctors receive no payment for any work related to this study.

10.2 ADDITIONAL CONSIDERATIONS

Not Applicable.

10.3 ABBREVIATIONS

The list below includes abbreviations utilized in this template. However, this list should be customized for each protocol (i.e., abbreviations not used should be removed and new abbreviations used should be added to this list).

AE	Adverse Event
ANCOVA	Analysis of Covariance
AR	Acute Rehabilitation
CFR	Code of Federal Regulations
CONSORT	Consolidated Standards of Reporting Trials
CRF	Case Report Form

DCC	Data Coordinating Center
DHHS	Department of Health and Human Services
DSMB	Data Safety Monitoring Board
DRE	Disease-Related Event
EC	Ethics Committee
eCRF	Electronic Case Report Forms
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
FFR	Federal Financial Report
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
IB	Investigator's Brochure
ICH	International Conference on Harmonisation
ICMJE	International Committee of Medical Journal Editors
IDE	Investigational Device Exemption
IND	Investigational New Drug Application
IRB	Institutional Review Board
ISM	Independent Safety Monitor
ISO	International Organization for Standardization
ITT	Intention-To-Treat
LSMEANS	Least-squares Means
MedDRA	Medical Dictionary for Regulatory Activities
MOP	Manual of Procedures
MSDS	Material Safety Data Sheet
OHRP	Office for Human Research Protections
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SOA	Schedule of Activities
SOC	Standard of Care
SOP	Standard Operating Procedure
SAR	Sub-Acute Rehabilitation
SUS	System Usability Scale
TKA	Total Knee Arthroplasty
UP	Unanticipated Problem
US	United States

Protocol Amendment History

The table below is intended to capture changes of IRB-approved versions of the protocol, including a description of the change and rationale. A Summary of Changes table for the current amendment is located in the Protocol Title Page.

Version	Date	Description of Change	Brief Rationale

REFERENCES

Include a list of relevant literature and citations for all publications referenced in the text of the protocol. Use a consistent, standard, modern format, which might be dependent upon the required format for the anticipated journal for publication (e.g., N Engl J Med, JAMA, etc.). The preferred format is International Committee of Medical Journal Editors (ICMJE). Include citations to product information such as manufacturer's IB, package insert, and device labeling.

1. Chughtai M, Kelly JJ, Newman JM, et al. The role of virtual rehabilitation in total and unicompartmental knee arthroplasty. J Knee Sug 2019;32:105-110.

Appendix:

Appendix A: 2011 Knee Society Score

Appendix B: Patient Daily Log

Appendix C: System Usability Scale

Appendix D: DJO X4 Brace Patient Information

Appendix E: ***X4 smart post-op brace and motion intelligence application. PROCESS AND PATIENT ON-BOARDING***