A Prospective Study to Evaluate the ConforMIS iTotal® (CR) Knee Replacement System and iPoly XE Tibial Inserts

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Protocol Signature Page

This is to acknowledge that I have received the above-identified protocol, that I have read and understood its content, and that I agree to conduct the clinical trial in accordance with the procedures outlined therein.

Investigator Approval:

_____

Signature Date

_____

Print Name

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1. INTRODUCTION, BACKGROUND & OBJECTIVE

Osteoarthritis or other degenerative changes or injury can cause damage to the structures in the knee, causing pain and discomfort, and lessening the quality of life. Knee replacement, or knee arthroplasty, is a common surgical procedure performed to relieve the pain and disability resulting from osteoarthritis. In general, the surgery consists of replacing the diseased or damaged joint surfaces of the knee with metal and plastic components shaped to allow continued motion of the knee.

Today, over 600,000 patients undergo total knee replacement each year in the United States, a number that is projected to increase greatly over the next 20 years (Kurtz). Total knee replacement has been performed since 1964 and has been shown to be an effective, long-lasting procedure with good survivorship of the implants for patients with osteoarthritis. Despite, the excellent survivorship, there are still a significant percentage of patients that remain dissatisfied with their results. Studies report 14-39% of patients report some level of dissatisfaction with their knees post-surgically (Noble et al., Bourne et al., Suda et al.).

The iTotal CR total knee replacement system and iPoly XE have been cleared by the FDA and CE marked for the treatment of osteoarthritis (OA). This study is designed to evaluate the clinical outcomes of subjects who have recently undergone surgery with the iTotal® Cruciate Retaining (CR) Total Knee Replacement System (KRS) who have also had iPoly XE Tibial Inserts implanted.

2. DEVICE DESCRIPTION

The iTotal® CR KRS is a tri-compartmental semi-constrained knee prosthesis composed of three components: a Femoral Component, a Tibial Component, and a Patellar Component. The product design incorporates a bone preserving approach for the treatment of severe pain and/or disability of a knee damaged by osteoarthritis or trauma. It is intended for use in those patients whose condition cannot be appropriately or effectively addressed using a device that treats only one or two compartments of the knee (i.e. a unicompartmental, bicompartmental, or patellofemoral prosthesis).

Using patient imaging, a patient-specific implant is designed that best meets the geometric and anatomic requirements of the specific patient. The treatment allows for the placement of a cemented metallic device designed from the patient's natural bone geometry. This process allows definition of the shape and size of the femoral and tibial components of the implant, as well as the disposable instrumentation (Fitz).

The iTotal® CR knee is constructed of cobalt chrome and conforms to the surface of the patient's femoral condyle, replacing the damaged cartilage with a smooth articulating surface. Specifically, the femoral component and tibial tray are manufactured from cobalt chromium molybdenum alloy. The tibial insert being utilized in this study will be a highly-crosslinked, Vitamin-E enriched UHMWPE (iPoly XE).

Several key features of the iTotal are listed below.

- Minimally traumatic procedure
- Precise fit to ensure range of motion without impingement or overhang

- Complete cortical rim coverage
- Anatomic component alignment
- Disposable, patient-specific instrumentation
- Simple, reproducible surgical technique
- Potential for less post-operative pain and shorter post-operative recovery time

3. STUDY DESIGN

The study is prospective and single-center. Subjects will be implanted with an iTotal® CR Knee Replacement System in conjunction with an iPoly XE insert. The study will include a minimum of 50 subjects and a maximum of 60 subjects at a single center. The study site will be located in Germany.

4. STUDY DURATION

The study subjects will be followed for 10 years post implant. The follow-up visit schedule will include on-site visits at 12 weeks, 6 months, 1 year, 2 years, 5 years and 10 years post implant to follow the surgeon's normal standard of practice. At 3, 4, 6, 7, 8, and 9 years post-op data may be collected; these data can be collected via phone call/email and do not require a subject to visit the site.

5. STUDY ENDPOINTS

5.1. **Primary Endpoint**

The study primary endpoint is pain and function at 1 Year after implantation, as measured by:

1. Knee Society Clinical Rating Score
    1.1. Objective Knee Score
    1.2. Function Score
    1.3. Satisfaction Score
    1.4. Expectation Score

5.2. **Secondary Endpoints**

The study secondary endpoints are:

1. The Knee Injury and Osteoarthritis Outcome Score (KOOS)
2. Revision rates post-implantation
3. Incidence of major procedure–related and device-related complications including infection rate
4. Post-operative limb alignment if long leg x-rays available
5. Radiographic loosening, radiolucencies
6. Length of procedure
7. Length of hospital stay in hours (admission to discharge)
8. Blood loss during surgery & blood transfusion rates

6. INCLUSION AND EXCLUSION CRITERIA

6.1. **Inclusion Criteria**

1. Clinical condition included in the approved Indications For Use for the iTotal® CR

2. Osteoarthritis, as confirmed by the investigator's assessment of disease status at screening visit that warrants a TKR procedure. Disease status is assessed by Clinical and Radiographic assessment.
3. Willingness to participate in the clinical study, to give informed consent, and to attend all follow-up visits
4. > 18 years of age

6.2. **Exclusion Criteria**

1. Simultaneous bilateral procedure required
2. BMI > 40
3. Active malignancy (defined as a history of any invasive malignancy – except non-melanoma skin cancer), unless patient has been treated with curative intent and there have been no clinical signs or symptoms of the malignancy for at least 5 years
4. Poorly controlled diabetes
5. Neuromuscular conditions which prevent patient from participating in study activities
6. Active local or systemic infection
7. Immunocompromised
8. Fibromyalgia or other general body pain related condition
9. Rheumatoid arthritis or other forms of inflammatory joint disease
10. Loss of bone or musculature, osteonecrosis, neuromuscular or vascular compromise in the area of the joint to be operated on, to an extent that the procedure is unjustified
11. Diagnosed with or receiving treatment for Osteoporosis
12. Other physical disability affecting the hips, spine, or contralateral knee
13. Severe instability due to advanced loss of osteochondral structure
14. Prior arthroplasty of the affected knee, including High Tibial Osteotomy (HTO)
15. Compromised PCL or collateral ligament
16. Severe fixed valgus or varus deformity of >15º
17. Extensor lag > 15º
18. Fixed flexion contracture ≥ 15º
19. Unwilling or unable to comply with study requirements
20. Participation in another clinical study which would confound results
21. Allergy to any of the implant materials

7. SITE SELECTION

The site will be selected by a Site Selection Committee based on a set of defined criteria. The Site Selection Committee will be led by Clinical Affairs. The site selection criteria includes, but is not limited to:

- Interest in participating in the study as demonstrated by responsiveness
- Demonstrated technical and surgical skills with iTotal® CR device - Investigator must have completed a cadaver training at minimum prior to enrolling their first patient
- Sufficient patient volume to expect timely subject enrollment
- Ability to adhere to the standards of Good Clinical Practice (GCP) and Good Documentation Practice (GDP)
- Clinical study experience and resources that demonstrate good compliance with study requirements and timely, complete documentation of subject follow-up

- Willingness to allow personnel from ConforMIS (or its designee) access to the hospital records, Investigator's study records, data, and patient files as they pertain to the study

8. ENROLLMENT

Potential subjects are identified by the Investigator or study staff based on patients' clinical and radiographic assessments during regular medical care. The Investigator or study staff provides study information and the approved Informed Consent Form to potential subjects and answers any questions. Once the patient signs the consent form, they are assigned a unique subject identification number through the EDC system that is comprised of a five digit number starting with a two digit site number assigned by ConforMIS at the Site Initiation followed by a three digit subject number, assigned chronologically for the entire study. For example, at site 01, the first subject enrolled will receive number 01-001, followed by 01-002, 01-003, etc.

The Investigator and/or study staff assesses the subject against the Inclusion and Exclusion criteria to determine eligibility. Eligibility includes clinical assessments, radiographic assessments and a review of the subject's medical history. The radiographic assessments should include:

1. Knee x-ray 3 views – AP, lateral, sunrise or Merchant
2. If site has the technology, three-foot standing x-ray (full length, full weight bearing film) – AP view

If the subject is not eligible to participate in the study, the subject is not enrolled and is considered a screen failure. All screen failures are tracked by the site manually in a tracking spreadsheet and electronically in a clinical database. Patient identification numbers for screen failures are not to be re-used.

The following Case Report Forms are required for all screen failures:

- SUBJECT INFORMATION
- INCUSION/EXCLUSION CRITERIA

If the subject is eligible to participate in the study, the subject is enrolled.

9. SCHEDULE OF EVALUATIONS BY VISIT

A table displaying the Schedule of Evaluations is in Appendix A. Enrolled subjects will complete each visit in the schedule of evaluations.

9.1. Pre-operative Visit (Up to 4 months prior to Surgery)

Many of the screening assessments required to ensure subject eligibility are also considered the pre-operative assessments. The results of the assessments are captured on the following Screening/Pre-operative Case Report Forms:

- SUBJECT INFORMATION
- INCLUSION/EXCLUSION CRITERIA
- MEDICAL HISTORY
- PAIN MEDICATIONS

- CONCOMITANT MEDICATIONS
- KNEE SOCIETY SCORE (Surgeon portion)

The subject completes the following questionnaires to assess pain and function as part of their pre-operative assessment:

- THE KNEE INJURY AND OSTEOARTHRITIS OUTCOME SCORE (KOOS)
- KNEE SOCIETY SCORE (Subject portion)

X-rays:

- 3 views – AP, lateral, sunrise or Merchant
- Three-foot standing x-ray (full length, full weight-bearing film): AP view

9.2. **Surgery Visit (Day 0)**

The Investigator surgically implants the iTotal® CR and iPoly XE inserts in compliance with the ConforMIS surgical training and iTotal® CR Instructions for Use.

The site completes the following Case Report Forms:

- SURGICAL SUMMARY
- DISCHARGE SUMMARY
- PAIN MEDICATIONS (update if changes have occurred)
- CONCOMITANT MEDICATIONS (update if changes have occurred)
- ADVERSE EVENTS / SERIOUS ADVERSE EVENTS (if any occur during surgery through discharge from hospital)

X-rays: None

9.3. **12-Week Follow-up Visit (± 2 weeks)**

At the 12-week follow-up visit, the Investigator or study staff performs a post-operative knee assessment and identifies any adverse events that have occurred since the subject was discharged from the hospital.

The site completes the following Case Report Forms:

- FOLLOW-UP FORM
- KNEE SOCIETY SCORE (Surgeon portion)
- PAIN MEDICATIONS (update if changes have occurred)
- CONCOMITANT MEDICATIONS (update if changes have occurred)
- ADVERSE EVENTS (if any)
    - REVISION FORM (if necessary)

The subject completes the following questionnaires to assess post-operative pain and function:

- THE KNEE INJURY AND OSTEOARTHRITIS OUTCOME SCORE (KOOS)
- KNEE SOCIETY SCORE (Subject portion)

X-rays:

- 3 views – AP, lateral, sunrise or Merchant

- Three-foot standing x-ray (full length, full weight-bearing film): AP view

9.4. **6-Month follow-up visit (± 3 weeks)**

At the 6-month follow-up visit, the Investigator or study staff performs knee assessments and identifies any adverse events that have occurred since the last visit.

The site completes the following Case Report Forms:

- FOLLOW-UP FORM
- KNEE SOCIETY SCORE (Surgeon portion)
- PAIN MEDICATIONS (update if changes have occurred)
- CONCOMITANT MEDICATIONS (update if changes have occurred)
- ADVERSE EVENTS (if any)
    - REVISION FORM (if necessary)

The subject completes the following questionnaires to assess post-operative pain and function:

- THE KNEE INJURY AND OSTEOARTHRITIS OUTCOME SCORE (KOOS)
- KNEE SOCIETY SCORE (Subject portion)

X-rays: None

9.5. **Year 1, 2, and 5 Follow-up Visits (± 2 months)**

At the 1-year, 2-year and 5-year follow-up visits, the Investigator or study staff performs a knee assessment and identifies any adverse events that have occurred since the subject's last visit.

The site completes the following Case Report Forms:

- FOLLOW-UP FORM
- KNEE SOCIETY SCORE (Surgeon portion)
- PAIN MEDICATIONS (update if changes have occurred)
- CONCOMITANT MEDICATIONS (update if changes have occurred)
- ADVERSE EVENTS (if any)
    - REVISION FORM (if necessary)

The subject completes the following questionnaires to assess post-operative pain and function:

- THE KNEE INJURY AND OSTEOARTHRITIS OUTCOME SCORE (KOOS)
- KNEE SOCIETY SCORE (Subject portion)

X-rays: Optional

9.6. **Year 3, 4, 6, 7, 8, and 9 Follow-up Visits (± 3 months)**

On the anniversary of the implant surgery for years 3, 4, 6, 7, 8, and 9, the Investigator or study staff assesses the subject for complications or adverse events, and specifically to determine if the iTotal® CR has been revised. It is not necessary for the subject to go to the clinic for a visit, as the site can obtain the data via direct communication with the subject (such as via telephone or email).

The site completes the following Case Report Form:

- FOLLOW-UP FORM
- ADVERSE EVENTS (if any)
    - REVISION FORM (if necessary)

X-rays: None

9.7. **Year 10 Follow-up Visit (± 4 months)**

On the 10-year anniversary of the implant surgery, the Investigator or study staff assesses the subject to determine if the iTotal® CR has been revised.

The site completes the following Case Report Form:

- FOLLOW-UP FORM
- PAIN MEDICATIONS
- CONCOMITANT MEDICATIONS
- ADVERSE EVENTS (if any)
    - REVISION FORM (if necessary)
- KNEE SOCIETY SCORE (Surgeon portion)
- SUBJECT DISPOSITION

The subject is asked to complete the following questionnaires to assess long term post-operative pain and function. Note that the subject should return to the clinic to complete these questionnaires. If a return to the clinic is not possible the patient will be provided the questionnaires either via mail, email, or through an internet site.

- THE KNEE INJURY AND OSTEOARTHRITIS OUTCOME SCORE (KOOS)
- KNEE SOCIETY SCORE (Subject portion)

X-rays: Optional

9.8. **Early Termination Visit**

In the event that the study subject ends their participation in the study prior to the 10-year visit, the investigator or designated study staff will complete the following CRFs:

- SUBJECT DISPOSITION
- PAIN MEDICATIONS
- CONCOMITANT MEDICATIONS
- ADVERSE EVENTS / SERIOUS ADVERSE EVENTS (if any)
    - REVISION FORM (if necessary)

The Investigator or designated study staff will make every attempt to complete the following CRFs (for both knees if necessary):

- THE KNEE INJURY AND OSTEOARTHRITIS OUTCOME SCORE (KOOS)
- KNEE SOCIETY SCORE (Subject and Surgeon portions)

10. SAFETY REPORTING

All Adverse Events (AEs) are recorded by the site from the day of surgery on the Adverse Event CRF and should be reported within 5 days of site becoming aware of the event. In addition, all Serious Adverse Events (SAEs) and Unanticipated Adverse Device Effects (UADEs) must be reported to ConforMIS or designee via telephone or email as soon as possible once discovered by the site. SAEs should be reported to ConforMIS within 3 working days, and UADEs should be reported to ConforMIS within 2 working days. The Investigator and investigative site will also be responsible for required reporting to the site's Institutional Review Board/Independent Ethics Committee (IRB/IEC).

For the purposes of this protocol, only those AEs categorized as Possible, Probable or Definite in relationship to the devices will be recorded. Those events that are Unlikely or Not Related to the device will not be collected. All Serious Adverse Events (SAEs) will be recorded regardless of the relationship to the device. Please see definitions below.

ConforMIS will be responsible for safety reporting as required by local regulations.

Adverse Event: Any untoward or unfavorable medical occurrence associated with the use of a medical product in a human patient, including any abnormal sign, symptom, or disease. Report only those AEs with Possible or above, relationship.

Definite:	Clear-cut temporal association and no other possible cause.
Probable:	Clear-cut temporal association and a potential alternative etiology is not apparent.
Possible:	Temporal association is less clear and other etiologies are also possible.
Unlikely:	Temporal association and the nature of the event is such that the study device is not likely to have had any association with the observed event (cause and effect relationship improbable but not impossible).
Not Related:	There is no temporal association and/or evidence exists that the event is definitely related to another etiology.

Serious Adverse Event: Any undesirable experience associated with the use of a medical product in a patient in which the patient outcome is: death, a life-threatening event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, a congenital anomaly/birth defect or requires intervention to prevent permanent impairment or damage.

Unanticipated Adverse Device Effect (21 CFR 812.3): Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the investigational plan or application (including a supplementary plan or application), or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of patients.

11. DATA MANAGEMENT

Each site is responsible for accurate, complete, and timely collection/recording of data using the CRF (or EDC system) provided. Data will be stored in a validated and secure database for analysis. ConforMIS will periodically review all data, and specifically adverse event data to determine interim revision rates, frequency of serious adverse device effects and subject outcomes. If missing data fields or incorrect data are identified, the site may be contacted to provide the missing/correct data. ConforMIS or a designee will provide Case Report Forms (paper and/or electronic) to the study sites, along with access to the EDC system.

12. MONITORING

ConforMIS or designee will monitor clinical sites to review source data, study conduct, and compliance to the protocol. Each site will be monitored shortly after beginning enrollment to ensure early identification and resolution of any issues. After the initial monitoring visit, the site will be monitored at a frequency determined by ConforMIS or designee based on a variety of variables including, but not limited to, the rate of enrollment, the number of issues identified that require follow-up, changes in site personnel, etc.

13. STATISTICAL METHODS

All statistical processing will be performed using SAS® Version 9.2 or later unless otherwise stated. Efficacy analyses performed using the intent-to-treat (ITT) population will be considered primary. Safety analyses will be performed on the safety population.

No imputations will be made for missing observations. Continuous variables will be summarized with sample size, mean, standard deviation, median, minimum, maximum, and 95% confidence intervals, as appropriate. Categorical variables will be summarized with frequency counts, percentages, and 95% confidence intervals, as appropriate.

Populations

The safety population will be comprised of all subjects for whom the procedure is initiated.

The ITT population will be comprised of all subjects for whom the procedure is completed.

Demographic and Baseline Evaluations

Demographic variables (age, gender, ethnicity, and race) will be recorded in the eCRF and summarized using descriptive statistics.

Efficacy Analysis

Primary Efficacy Analysis

There is one primary endpoint, change from baseline to 1-Year in KSS. Hypothesis testing of the primary endpoints will be conducted for the ITT population, and will be analyzed with paired t-test.

Secondary Efficacy Analyses

Secondary endpoints will be analyzed for the ITT population. Details of statistical testing for each endpoint will be further discussed in the Statistical Analysis Plan.

1. Change from baseline in KSS at years 2, 5 and 10 post-implantation
2. Change from baseline in KOOS at years 1, 2, 5 and 10 post-implantation
3. Post-operative limb alignment if long leg x-rays available
4. Length of hospital stay in hours (admission to discharge)
5. Blood loss during surgery
6. Transfusion rate

Supportive Efficacy Endpoints

1. Revision rates post-implantation
2. Radiographic loosening, radiolucencies
3. Length of procedure: Skin to Skin

Safety Analysis

All adverse events (AEs) occurring during the study will be recorded and classified. For the safety population, all reported AEs will be summarized by the number of subjects reporting AEs, severity, relationship to procedure, relationship to device, and seriousness. For summaries of AEs by relationship or severity, each subject will be counted only once using the event with the greatest relationship or highest severity.

In addition to overall AE summaries, AEs will be summarized for the following study periods:

- Day of procedure to 6 months post procedure
- Annual summaries (1 Year, 2 Year, etc.) from day of procedure

Serious adverse events (SAEs) will be summarized by group, severity, relationship to procedure, and relationship to device. SAEs will also be listed by subject.

All information pertaining to AEs noted during the study will be listed by subject.

Sample Size Determination

The sample size for this study was not based on a power analysis. However, a sample size of up to 50 subjects is considered to provide adequate estimation of the study endpoints.

14. SUBJECT PROTECTION

Data will be de-identified on forms and in the clinical database, and subjects will be identified only by a code or subject number. All information and data sent to ConforMIS or designee concerning subjects or their participation in this study will be considered confidential, and confidentiality shall be observed by all parties involved at all times during the study. All data used in analysis and reports will be used without identifiable reference to the subject. All data will be secured against unauthorized access. The Investigator and investigative site will be responsible for compliance with all local privacy regulations.

15. ETHICAL CONSIDERATIONS

The protocol and Informed Consent Form must be approved by a central IRB or the IRB/IEC for the institution where the study is conducted. Each subject shall give informed consent in a form

and manner that meets all IRB/IEC requirements. All patients must be informed that the device is available commercially and that participation in the clinical study is not required for them to be treated with the device. Investigators shall agree to conduct the study in compliance with the provisions of the Declaration of Helsinki and with ICH/GCP Standards.

In compliance with the Food and Drug Administration Amendments Act of 2007 (FDAAA), this study will be listed in www.clinicaltrials.gov.

16. REPORTS

A final study report shall be prepared and provided to all investigative sites for submission to their IRB/IEC. The final study report will be made a permanent record in the ConforMIS document control system.

17. LITERATURE

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18. APPENDIX A – Schedule of Evaluations

Evaluation	Screening/ Pre-Op	Surgery & Discharge	12 Week Follow-up	6 Month Follow-up	Year 1, 2, 5 Follow-up	Year 3, 4, 6, 7, 8, 9 Follow-up	Year 10 Follow-up
Visit window	**Up to 4 months prior to surgery**	**-**	**± 2 weeks**	**± 3 weeks**	**± 2 months**	**± 3 months**	**± 4 months**
Subject Information	**X**						
Inclusion/Exclusion Criteria	**X**						
Medical History	**X**						
Pain Medications	**X**	**X**	**X**	**X**	**X**		**X**
Concomitant Medications	**X**	**X**	**X**	**X**	**X**		**X**
Knee Society Score^	**X**		**X**	**X**	**X**		**X**
Radiographic Evaluation*	**X**		**X**		**O**		**O**
Knee Injury & Osteoarthritis Outcome Score (KOOS)^	**X**		**X**	**X**	**X**		**X**
Surgical & Discharge Summary		**X**					
Adverse Events		**X**	**X**	**X**	**X**	**X**	**X**
Follow-Up			**X**	**X**	**X**	**X**	**X**

X=Protocol mandated tests; O=Optional tests

^KSS & KOOS Questionnaires should be completed for ALL iTotal knees and on the contralateral knee if the contralateral knee has previously had standard TKA performed.

*Radiographic Evaluation includes:

1. Knee x-ray 3 views – AP, lateral, sunrise or Merchant
2. If available, three-foot standing x-ray (full length film with full weight bearing) – AP view

PROTOCOL HISTORY

Protocol Version	Protocol Date	Updated by:	Changes Made:
1.0	30 June 2016	Marc Quartulli	Initial release