# Stryker NTX Registry

# Scorpio NRG, Triathlon Total Knee, Triathlon PKR with X3 Insert

# International Multicentre Outcomes Register

Date: February 2011
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# International Multicentre Outcomes Register

# Protocol

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Date: February 2011
Reference: K-S-044

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# Stryker NTX Registry

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# International Multicentre Outcomes Register

# Protocol Summary

| | |
|---|---|
| **Title** | Stryker NTX Registry – International Multicentre Outcomes Register<br><br>(**N**RG, **T**riathlon and **X**3 registry) |
| **Short Title** | NTX Registry |
| **Protocol Number** | K-S-044 |
| **Phase** | Post-market |
| **Surveillance design** | International multicentre, prospective follow-up of a consecutive series of patients |
| **Objectives** | Provide outcomes information with regard to surgical and implant performance and patient clinical outcomes of the patients who are eligible for a either a Total Knee Arthroplasty (TKA) replacement surgery involving either:<br>• Scorpio NRG Total Knee System with X3 insert<br>• Triathlon Total Knee System with X3 insert<br><br>or Partial Knee Resurfacing (unicompartmental knee arthroplasty, UKA) involving:<br>• Triathlon PKR (Partial Knee Resurfacing) System with X3 insert |

| | |
|---|---|
| **Study Duration** | The length of surveillance and patient visit schedule is based on the routine procedures of the institution. The surveillance system is set- up to record data at 1, 3, 5, 7 and 10 years follow-up.<br>The implant will be followed for 10 years or until it has to be revised, the patient dies or emigrates (unless the patient withdraws participation).<br>Definition of revision: at least one part of the implant has to be revised. |
| **Participating institutions** | Up to sixteen institutions willing to participate in the Stryker Clinical Registry need to recruit at least 20 patients and maximum 100 patients. Institutions must fulfil the local and international applicable regulatory requirements. Sufficient human and technical resources in the centre are expected to ensure optimal data collection. |
| **Number of Patients** | Up to 1600 patients will be included (20-100 per centre).<br>All patients eligible for either<br>a Total Knee Arthroplasty (TKA) replacement surgery involving either:<br>• Scorpio NRG Total Knee System with X3 insert<br>• Triathlon Total Knee System with X3 insert<br>or Partial Knee Resurfacing (unicompartmental knee arthroplasty, UKA) involving:<br>• Triathlon PKR (Partial Knee Resurfacing) System with X3 insert<br>who have been informed about this outcomes register and who freely consent to participate (with the signed and dated inform consent) will be enrolled in the register. Patients will be enrolled prospectively. |

| | |
|---|---|
| **Inclusion Criteria** | 1. Patients requiring primary TKA, suitable for the use of the Scorpio NRG with X3 insert or Triathlon Total Knee System with X3 insert, or, patients requiring partial knee resurfacing (unicompartmental knee) suitable for the use of the Triathlon PKR (Partial Knee Resurfacing) System with X3 insert<br>2. Patients who understand the conditions of the outcomes registry and are willing and able to comply with the standard post- operative evaluations and the prescribed rehabilitation.<br>3. Patients who signed the Informed Consent Form (approved by Ethics Committee if required) prior to surgery. |
| **Exclusion Criteria** | None |
| **Patient ID** | Each patient participating in the registry will be allocated a unique number for the duration of the surveillance. The investigator will maintain a personal subject identification list (subject numbers with the corresponding subject names) to enable records to be identified. |

**Study Devices**

All components of the Scorpio NRG Total Knee System (with CR and PS insert), Triathlon Total Knee System (with CR and PS insert and CS insert) as well as the Triathlon Partial Knee Resurfacing System (Triathlon PKR) with X3 used in this clinical registry have been CE marked (CE0086) according to the Medical Device Directive 93/42/EEC and therefore are approved for sale on the European market.

**Scorpio NRG™ Total Knee**: The following implants from the product Portfolio can be included:

| | |
|---|---|
| Femur | • CR Femoral Component – cemented / cementless<br>• PS Femoral Component - cemented / cementless |
| Tibia (fixed bearing only) | • Scorpio Tibial Baseplate – cemented / cementless |
| Insert | • NRG CR (Cruciate Retaining) – X3<br>• NRG PS (Posterior Stabilising) – X3 |
| Patella resurfacing (optional) | • Medialized / Concentric / Universal Dome - X3 |

**Triathlon™ Total Knee**: The following implants from the product Portfolio can be included:

| | |
|---|---|
| Femur | • CR Femoral Component – cemented / cementless<br>• PS Femoral Component - cemented / cementless |
| Tibia (fixed bearing only) | • Primary Tibial Baseplate – cemented / cementless<br>• Universal Baseplate - cemented |
| Insert | • Triathlon™ CR (Cruciate Retaining) – X3<br>• Triathlon™ CS (Cruciate Substituting) – X3<br>• Triathlon™ PS (Posterior Stabilising) – X3 |
| Patella resurfacing (optional) | • Cemented - Symmetric / Asymmetric - X3 |

**Triathlon™ PKR Partial Knee Resurfacing System:** The following implants from the product Portfolio can be included:

| | |
|---|---|
| Femur | • Triathlon™ PKR femur (left medial-LM/right lateral-RL) – cemented |
| Tibia (fixed bearing only) | • Triathlon™ PKR Baseplate (LM/RL) – cemented |
| Insert | • Triathlon™ PKR tibia insert (LM/RL) – X3 |

| | |
|---|---|
| **Analysis of results and reports** | Results will be analysed by Stryker Clinical. There will be 2 types of annual reports on register data. i) Stryker Clinical will prepare a report on the overall dataset ii) each Investigator will receive a confidential report from data from their own institute including benchmarks relative to the average without disclosure of the results of other departments.<br><br>Possible analyses of the data include:<br>• **Safety** during follow-up and **Survivorship** as described by Kaplan-Meier survival curves:<br>o Adverse events: All intra-operative and post-operative adverse events will be recorded.<br>o Survivorship with regard to the revision of the entire system or system components (e.g. insert only, tibia base plate only)<br>o Survivorship with regard to re-operation without component exchange<br><br>• **Patient clinical outcome**<br>o Standard clinical parameters and KSS (Knee Society Score) as well as patient questionnaires (EQ5D (EuroQol Group) and KOOS (Knee Injury and Osteoarthritis Outcome Score)) preoperatively and each follow-up visit. |
| **Statistical Methodology** | • Survival will be described by Kaplan-Meier survival curves<br>• Frequency and percent distributions will be presented in tabular form for categorical variables. The mean, standard deviation, minimum and maximum values will be presented for quantitative variables |

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# Evaluation Schedule

The evaluation schedule is based on the routine procedures of the institution.

| Evaluation | Pre-op* | Intra-op | 1 yr post-op. | 3 yr post-op. | 5 yr post-op. | 7 yr post-op. | 10 yr post-op. |
|---|---|---|---|---|---|---|---|
| **Time window** | Up to - 4 months* | N/A | ± 3 months | ± 6 months | ± 6 months | ± 6 months | ± 6 months |
| Inc./Ex. Criteria | **X** | | | | | | |
| Pre-OP | **X** | | | | | | |
| Surgical Details | | **X** | | | | | |
| KSS | **X** | | **X** | **X** | **X** | **X** | **X** |
| KOOS | **X** | | **X** | **X** | **X** | **X** | **X** |
| EQ-5D | **X** | | **X** | **X** | **X** | **X** | **X** |
| Adverse Events, Termination | **As and when required** | | | | | | |

* Pre-OP: Date of or any time post the date of written informed consent up to 4 months prior to date of surgery.

KSS: The Knee Society Score is usually reported as the two scores, Knee Score and Function Score. The Knee Score consists of points given for pain, range of motion, and stability. The Function Score consists of points given for the ability to walk on level surfaces, and the ability to ascend and descend stairs.

KOOS: KOOS is a patient-administered and developed as an instrument to assess the patients' opinion about their knee and associated problems. KOOS consists of 5 subscales; Pain, other Symptoms, Function in daily living, Function in sport and recreation (Sport/Rec) and knee related Quality of life QOL.

EQ-5D: The EQ-5D is a standardized instrument for use as a measure of health outcome. The EQ-5D is commonly used in health economics as a variable in the quality-adjusted life year calculation to determine the cost effectiveness of a health treatment.

# 1 INTRODUCTION

Knee replacement arthroplasty has consistently shown to be successful in relieving pain and improving function for those experiencing difficulties of degenerative joint disease. In recent years, patient quality of life and return to function have become of greater importance in assessing the success of joint replacement surgery. The higher demands placed on current and new implants by the younger, typically more active patient population emphasizes the importance for prostheses that show consistent long-term results.

Knee arthroplasty can either be for Total Knee Arthroplasty (TKA), where there is replacement of both tibial and both femoral condyles, or only for Partial Knee Resurfacing (PKR) where only one tibial condyle and one femoral condyle are replaced (unicompartmental knee) if one compartment is affected.

Stryker's Knee System portfolio includes the Scorpio NRG and Triathlon Total Knee Systems and the Triathlon Partial Knee Resurfacing (PKR) System.

**Single Radius and Soft Tissue guided motion**

Many knee prostheses have been shown to internally and externally rotate around a lateral or central point rather than follow the natural medial pivot that the normal knee exhibits. This is probably due to a number of factors such as the shape of the implant, surgical technique and the remaining soft tissue pathology. But this high degree of variability of internal-external rotation, as with the presence of paradoxical anterior motion, can not only lead to issues with wear and longevity but also with function and ultimately a patient's lifestyle.

Guided motion knees are designed to try and force the knee to move in a particular way – e.g. a medial pivot knee or mobile bearing. The problem with that, though, as the literature would suggest, is that quite often the knee wants to work in a different way. The affect is that this can create a "kinematic conflict" whereby the soft tissue is fighting against what the implant is trying to force it to do. In such cases this has been shown to lead to early wear, further pathology of the soft tissue and subsequent failure of the implant.

The Stryker Knee Systems named above follow the philosophy of Soft Tissue Guided Motion. The premise for this is that the knee will "find its own way" in its new kinematic environment and engineers and surgeons have to give the soft tissue the best possible environment to optimize the situation. By keeping the collaterals tight and the knee stable during the functional flexion arc, the Single Radius principle (creates the best environment for the body to find its natural internal-external centre of rotation. By allowing the collaterals to work the way that they were designed to, the femur is able to rotate in a more "natural" and physiological manner. This allows predictable motion pathways which not only have benefits for function, but also for longevity as they reduce sliding – a key cause of wear.

The Single Radius principle is fundamental in providing stability to the knee in its new environment and is the major contributor in allowing soft tissue guided motion.

There are additional features of Stryker's 4th generation knees that have been incorporated into the implant design features to assist with this principle.

One of the key features is the introduction of a Rotary- or Spherical Arc machined into the insert surface in the Triathlon and Scorpio NRG designs, respectively. This is a 3-dimensional approach to creating an articular surface that compliments the femoral design. This concept essentially allows greater freedom of rotation without sacrificing conformity. By reducing the rotational constraint inherent in most conventional multi radius designs the replaced knee is assisted in adapting to its new environment and allows the soft tissue to dictate the motion necessary to achieve the patients' functional goals.

The Single Radius of the femoral component provides gap balancing throughout the functional ROM which provides the stability and predictable motion required. In addition, the rotary arc and Single Radius concepts complement each other to guide the knee and ensure optimization of contact areas with minimal sliding (conformity without constraint).

The Triathlon PKR system has been designed with the same design philosophy and rational as the Triathlon and Scorpio NRG Total Knee System and is therefore an alternative solution for patients that suffer from isolated compartmental wear.

The main difference between the Triathlon Total Knee system and the Scorpio NRG Total Knee system is beside the use of a single A/P radius also the use of a single M/L radius design for the Scorpio NRG realizing a large contact area and higher rotational freedom in the two orthogonal planes.

The Single Radius and Soft Tissue guided motion philosophy, coupled with the latest generation highly cross-linked polyethylene (X3) as the material for the articulating surface has the potential to offer patients a longterm solution to their knee disability. X3 polyethylene preserves the mechanical strength, resists oxidation and shows extremely low wear rates.

**Summary**

The higher demands placed on current and new implants by the younger typically more active patient population emphasizes the importance for prostheses that show consistent long-term results. As the Stryker Knee systems are evolutionary in design and based on proven concepts and prior implant strategies, it is anticipated that they will demonstrate efficacy and safety in the long-term, however as for all new technology or design, a close overview of the long term performance and outcome is essential to prove this.

The aim of this Stryker Clinical Registry is to determine the Scorpio NRG, Triathlon and X3 component survivorship over years within a large European multicentre user group.

# 2 SURVEILLANCE DESIGN

This is a prospective international multicentre follow-up of a consecutive series of patients. The surveillance register will be conducted in accordance to the applicable regulatory requirements including local health and personal data protection laws. Where applicable, Ethics Committees will be informed about the register and if required, Ethics Committee authorisation/favourable opinion will be asked prior to the register start. If a full Ethic

Committee approval is not required, then a written confirmation of this is required from the responsible EC stating that data can be collected from that particular site.

All institutions willing to participate in the register, able to recruit at least 20 patients (up to 100 patients) and fulfilling the local and international applicable regulatory requirements can be considered for participation. Sufficient human and technical resources are expected in the institution to ensure optimal data collection.

All patients eligible for a knee arthroplasty surgery involving the Scorpio NRG or Triathlon Total Knee System or Triathlon PKR Partial Knee Resurfacing (all with X3 inlay), who have been informed about this surveillance register and who freely consent to participate, will be enrolled in the register (written informed consent described in Appendix II will be obtained from the patients).

# 3 OBJECTIVES & METHODS

The objective of this registry is to provide outcomes information with regard to surgical and implant performance and patient clinical outcomes of the patients who are eligible for a either a Total Knee Arthroplasty (TKA) replacement surgery involving the Scorpio NRG or Triathlon Total Knee System or Triathlon PKR Partial Knee Resurfacing (unicompartmental knee arthroplasty, UKA), all of which with X3 inlay.

The register will follow the standard clinical procedures used by the institutions for patient selection for knee arthroplasty surgery, patient surgery and patient follow-up. Therefore there will be, with regard to this register, no additional assessment, examination, procedure or follow-up visits compared to those usually performed in the institution (routine standard normal procedures).

# 4 DESCRIPTION OF THE DEVICES

All components of the Scorpio NRG System (with CR and PS insert), Triathlon Total Knee System (with CR and PS insert and CS insert) as well as the Triathlon Partial Knee Resurfacing System (Triathlon PKR) used in this clinical registry have been CE marked (CE0086) according to the Medical Device Directive 93/42/EEC and therefore are approved for sale on the European market.

Patients will either receive **Scorpio NRG Total Knee, Triathlon™ Total Knee** or **Triathlon™ PKR Partial Knee Resurfacing System,** combined with a respective X3 insert.

**Please note that in the Stryker NTX Registry ONLY X3 inserts are approved!**

The product component sizes are listed in APPENDIX III - PRODUCT COMPONENT SIZES.

## 4.1 Scorpio NRG Total Knee

### 4.1.1 Femoral Component

The Scorpio NRG® femoral components are manufactured from cobalt chromium alloy (ASTM F75) and are available in CR (cruciate retaining) and PS (posterior stabilising) design, both of which are available in cemented and cementless versions and left and right configurations.

These components have been designed to mimic the normal femoral condylar geometry. These components employ a single medial lateral radius, which corresponds with the bearing surface of the intended articulating tibial counterpart. This helps to maintain contact between the femoral condyles and the tibial insert surface throughout the range ofmotion.

In the cemented version, the interior surface of the components contains a waffle pattern for the cement interface. In the cementless version, the interior surface is grit blasted plus a HA (hydroxyapatite) coating.

The femoral components are available in nine proportional sizes 3, 4, 5, 6, 7, 8, 9, 11 and 13.

### 4.1.2 Tibia Baseplate

The cemented Scorpio® Primary Knee System Tibial Baseplate is manufactured from cobalt-chromium alloy. The Scorpio® Primary Tibial Baseplate is neutral in configuration and the keel of the tibial tray is designed with normalizations for rotational stability and cement interdigitation. The tibial component has a central delta keel with normalizations to improve stability and facilitate cement pressurization.

The Scorpio baseplate is available in cemented and cementless versions.

In the cemented version, the undersurface of the tibial tray has a waffle structure and is designed for use with PMMA bone cement and is available in eight proportional sizes (3, 4, 5, 6, 7, 9, 11, 13).

The cementless version is also available as either a waffle structure with HA (hydroxyapatite) coating, a beaded surface, or a beaded surface with PA (Peri-Apatite) coating. All are available in various sizes.

### 4.1.3 Insert

The tibial insert components are available in CR and PS designs. Both designs are manufactured from ultra high molecular weight polyethylene (ASTM F648). Highly crosslinked sequentially linked X3 polyethylene inserts are to be used in all study patients.

X3 polyethylene is manufactured through a proprietary process where the PE receives 30 kiloGrays of gamma radiation, which generates free radicles and cross-linking in UHMWPE prior to machining. The PE is then annealed below melting point to promote cross-linking

and maintains mechanical strength, crystallinity, and density. This also stabilises the free radicles. This process is repeated three times.

For Scorpio NRG, a proprietary rotary machining process used on the articulating surface of the tibial insert provides for improved rotation of components (Spherical Arc Design). In keeping with the design theory the tibial insert component maintains a single medial-lateral radius with 5 degrees of freedom. The surface incorporates a posteriorly sloping raised tibial eminence. The insert is assembled to the tibial tray component intraoperatively via a locking wire mechanism. The locking wire is manufactured from wrought cobalt chromium alloy (ASTM F90). The inserts are available in five sizes (3, 5, 7, 9, 11). Each size is available in seven thicknesses 8mm, 10mm, 12mm, 15mm, 18mm, 21mm and 24mm.

### 4.1.4 Patella Component

The use of a patellar component is optional. The Scorpio® System Patellar component is manufactured from highly crosslinked (X3) polyethylene and is available with a medialized dome design in 4 sizes, a concentric dome in 4 sizes and universal dome in 6 sizes.

## 4.2 Triathlon Total Knee

### 4.2.1 Femoral Component

The femoral component fabricated from cast cobalt-chromium-molybdenum alloy.

The femoral component is available in CR (cruciate retaining) or Triathlon PS (Posterior Stabilising) design, both of which are available in cemented and cementless (beaded or beaded with Peri-Apatite) versions.

The interior surface of the femoral component intended for use with bone cement is grit-blasted to increase the surface roughness, which is entended to promote interdigitation of the Polymethylacrylate (PMMA) bone cement with the surface texture and the opposing bone.

The CR femoral design features cast-in pegs to help in femoral component placement, and to provide rotational stability.

The Triathlon CR: intended for use in combination with the Triathlon CR (cruciate retaining) or Triathlon CS (Cruciate Substituting) tibial inserts. The Triathlon PS: intended for use in combination with the Triathlon PS (Posterior Stabilising) tibial inserts

There are 8 sizes available in both CR and PS designs (#1-8). All designs are available in left and right configurations.

The femoral component is a Single Radius design with a deepened trochlea; bevelled intercondylar region; and shortened, flared posterior condyles to facilitate fit, stability, and motion. The femoral component has a Single Radius of curvature centered about the epicondylar axis and is constant from 10° to 110°, promoting ligament balance and stability and rotation. The Triathlon femoral component has a narrowed M/L dimension with a 7°

anterior flange. There are various instruments available suitable for all approaches (Medial Parapatellar, Mid-vastus, Sub-vastus, Triathlon MIS approach).

### 4.2.2 Tibia Baseplate

Patients will receive either Triathlon Primary Tibial Baseplate or Triathlon Universal Tibial Baseplate. Both are fabricated from cast cobalt chrome molybdenum alloy and are neutral in configuration.

The Triathlon Primary Tibial Baseplate is available in cemented and cementless (beaded or beaded with Peri-Apatite) versions. The undersurface of the tibia baseplate intended for use with bone cement is grit-blasted for interdigitation with PMMA bone cement. The tibial component has a central delta keel with normalizations to improve stability and facilitate cement pressurization. The tibia baseplate has an Anti-Rotation Island to facilitate assembly and reduces micromotion. There is a robust locking mechanism (locking wire) with precision locking geometry. There are 8 sizes available (# 1-8).

The Triathlon Universal Tibial Baseplate is available as cemented version and in 8 sizes (# 1-8).

### 4.2.3 Insert

The Triathlon tibial insert components are available in CR (Cruciate Retaining), CS (Cruciate Substituting) and PS (Posterior Stabilising) designs. All designs are manufactured from ultra high molecular weight polyethylene UHMWPE (ASTM F648), highly crosslinked (sequentially linked) X3™ polyethylene inserts.

The Triathlon polyethylene insert is milled in a rotary arc, rather than in a linear fashion. This facilitates conformity, congruity, and stability, as well as rotation and flexion, to minimize wear and improve longevity.

The Triathlon CR insert is available in 8 sizes (#1-8), and in 5 thicknesses (9, 11, 13, 16, 19mm). The Triathlon CS insert is available in 8 sizes (#1-8), and in 7 thicknesses (9, 11, 13, 16, 19, 22, 25mm). The Triathlon PS insert is available in 8 sizes (#1-8), and in 7 thicknesses (9, 11, 13, 16, 19, 22, 25mm).

### 4.2.4 Patella Component

The use of a patella component is optional. The Triathlon System patella component is also manufactured from Highly crosslinked sequentially linked X3™ polyethylene and is available in symmetric and asymmetric design. The asymmetrical patella component is anatomic in shape to improve bone coverage and is available in sizes that vary in outer dimensions as well as in thickness. A simple symmetric dome implant is also available.

The cemented symmetric X3 component is available in 6 sizes. The cemented asymmetric X3 component is available in 5 sizes.

## 4.3 Triathlon PKR Partial Knee Resurfacing System

### 4.3.1 Femoral Component

The Triathlon PKR femoral component is fabricated from cast-cobalt-chromium- molybdenum alloy and has two fixation pegs. The system is intended for cemented fixation. The bone/cement facing surface of the component is grit blasted and the articulating surface is highly polished.

The Triathlon PKR femoral component was designed with the same philosophy and rational at the Triathlon Total Knee System to have a Single Radius to recreate the natural movement of the epicondyle (in 10°-110° range). Triathlon PKR Partial Knee Resurfacing System incorporates a simple two-step gap balancing system to help balance the flexion and extension gaps so the femoral component is positioned well and normal physiologic ligament tension may be restored.

It is available in 6 sizes ranging from Size 1 to Size 6 in right lateral/left medial and left lateral/right medial configurations.

### 4.3.2 Tibia Baseplate

The Triathlon PKR tibia baseplate is fabricated from cast-cobalt-chromium-molybdenum alloy. The system is intended for cemented fixation.

The underside of the tibial component contains a cement recess, a round peg and an angled peg for cement fixation and to provide stability. The inside of the tray has tabs and lip for locking the tibial insert in place. The surface finish of the underside of the baseplate is grit blasted and the topside is bead blasted.

It is available in 6 sizes ranging from Size 1 to Size 6 in right lateral/left medial and left lateral/right medial configurations.

### 4.3.3 Insert

The Triathlon PKR inserts are manufactured from ultra high molecular weight polyethylene (ASTM F648). Highly crosslinked (sequentially linked) X3™ polyethylene inserts.

The articular surface of the Triathlon PKR insert is designed to allow the following kinematics: Range of Motion 0° hyperextension to 135° flexion.

The Triathlon PKR insert is available in six sizes with thicknesses of 8mm, 9mm, 10mm and 12mm for the right lateral/left medial and left lateral/right medial compartments.

# 5 SELECTION OF PATIENTS

## 5.1 Participating Institutions

Up to sixteen institutions willing to participate in the Stryker Registry need to recruit at least 20 patients and maximum 100 patients. Institutions must fulfil the local and international applicable regulatory requirements. Sufficient human and technical resources in the centre are expected to ensure optimal data collection. Site selection will be performed according to Stryker Clinical procedures.

## 5.2 Number of patients

Up to 1600 patients who will receive a Total Knee Arthroplasty (TKA) replacement surgery involving either:

- Scorpio NRG Total Knee System with X3 insert
- Triathlon Total Knee System with X3 insert

or Partial Knee Resurfacing (unicompartmental knee arthroplasty, UKA) involving:

- Triathlon PKR (Partial Knee Resurfacing) System with X3 insert

will be enrolled in the register. Patients will be enrolled prospectively.

## 5.3 Patient selection criteria

All patients in a participating centre matching all of the inclusion criteria (no specific exclusion criteria) and who receive either the (TKA) surgery involving the Scorpio NRG or Triathlon Total Knee System with X3 inlay or a partial knee resurfacing (unicompartmental knee) involving the Triathlon PKR (Partial Knee Resurfacing) System will be recorded in the Stryker Registry.

### 5.3.1 Inclusion criteria

Patients suitable for inclusion in the outcomes registry will be those fulfilling all the following selection criteria:

1. Patients requiring primary TKA, suitable for the use of the Scorpio NRG with X3 insert or Triathlon Total Knee System with X3 insert, or, patients requiring partial knee resurfacing (unicompartmental knee) suitable for the use of the Triathlon PKR (Partial Knee Resurfacing) System with X3 insert
2. Patients who understand the conditions of the outcomes registry and are willing and able to comply with the standard post-operative evaluations and the prescribed rehabilitation.

3. Patients who signed the Informed Consent Form (approved by Ethics Committee if required) prior to surgery.

   The patient will be informed by the Investigator (or his designated representative) of the purpose of the data collection. The patient will be informed that his/her medical records are subjected to review as necessary. The confidentiality of the patient will be maintained at all times and the collected data will be anonymous. The patient will be told that he/she is free to refuse the collection of his/her clinical data and to withdraw from the Surveillance at any time without compromising future medical care. A signed Patient Informed Consent will be obtained prior to patient participation (**APPENDIX II - PATIENT INFORMATION SHEET AND INFORMED CONSENT**).

### 5.3.2 Exclusion criteria

There are no exclusion criteria for the NTX Registry

## 5.4 Patient ID

Each patient participating in the registry will be allocated a unique number for the duration of the surveillance. The investigator will maintain a personal subject identification list (subject numbers with the corresponding subject names) to enable records to be identified.

# 6 STUDY DURATION

It is anticipated that the patients shall be recruited within a 12 month period at each participating centre. The length of surveillance and patient visit schedule is based on the routine procedures of the institution. The surveillance system is set-up to record data at pre-operative, intra-operative and 1 year, 3 years, 5 years, 7 years and 10 years follow-up.

# Visit schedule

| VISIT | TIME WINDOW |
|---|---|
| Pre-op. | Date of or any time post the date of written informed |
| Operation | N/A |
| 1 year post-op. | ± 3 months |
| 3 years post-op. | ± 6 months |
| 5 years post-op. | ± 6 months |
| 7 year post-op | ± 6 months |
| 10 years post-op. | ± 6 months |

## 6.1 Patient Evaluations

Patients will be assessed pre-operatively, per-operatively and post-operatively. The follow-up intervals will be the normal routine of the institutions.

### 6.1.1 Pre-operative Evaluation

- **Clinical History**

- Patient ID (Register, Site, Subject) e.g. TRI-01-001
- Date of birth, weight, height, Gender
- Visit Date
- Cigarette and Alcohol use
- Previous surgery to knee planned for operation
- Primary diagnosis
- Pain medication (in last 48 hours)

**- Clinical Evaluation**

- Patient ID (Register, Site, Subject)
- Operative side
- Date of informed consent signed
- Inclusion / Exclusion criteria
- KSS (Knee Society Score)
- Knee Injury and Osteoarthritis Outcome Score (KOOS) and EQ5D

### 6.1.2 Intra-operative Evaluation

**- Surgical details**

- Patient ID (Register, Site, Subject)
- Surgery Date
- Operative Side
- Surgical approach
- Navigation used
- Soft tissue release
- Type of Anesthesia
- Duration of surgery
- Intra-operative adverse events
- Components used and sizes
- Systemic antibiotic prophylaxis

### 6.1.3 Post-operative Evaluation

Patients will be assessed post operatively as the schedule for follow-up routine of the participating centre.

**- Clinical Evaluation**

- Patient ID (Register, Site, Subject)
- Date of assessment
- Adverse events
- Pain medication (in last 48 hours)
- KSS
- KOOS and EQ5D

### 6.1.4 Adverse events and device removal events

- Patient ID (Register, Site, Subject)
- Onset date
- When Did the event occur (Intra-op, Post-op)
- Operative site events
- Systemic events
- Device/procedure related
- Seriousness
- Treatment
    - Revision/Removal of the entire system or system components
    - Reoperations without component exchange
    - Other treatment
- Resolution of event

### 6.1.5 Termination

- Date of termination of Surveillance
- Reason for termination

## 7 ADVERSE EVENTS

The investigator is required to document all operative site and general medical adverse events as well as elective surgery involving other joints over the course of the 10 year surveillance period. Data to be collected includes date of occurrence, date diagnosed, type of complication and treatment.

## 7.1 Definitions

The following definitions are according to ISO 14155 from 2011.

### 7.1.1 Adverse event (AE)

"Any untoward medical occurrence, unintended disease or injury, or untoward clinical signs (including abnormal laboratory findings) in subjects, users or other parties, whether or not related to the investigational medical device

NOTE : This definition includes events related to the procedures involved."

Surgical procedures themselves are not adverse events; they are therapeutic measures for conditions that require surgery. The condition for which the surgery is required is an adverse event, if it occurs or is detected during the Register follow-up period.

### 7.1.2 Serious adverse event (SAE)

"Adverse event that

a) led to death,

b) led to serious deterioration in the health of the subject, resulting in

1) a life-threatening illness or injury, or

2) a permanent impairment of a body structure or a body function, or

3) in-patient or prolonged hospitalization, or

4) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,

c) led to foetal distress, foetal death or a congenital abnormality or birth defect

NOTE: Planned hospitalization for a pre-existing condition, or a procedure required by the protocol, without serious deterioration in health, is not considered a serious adverse event."

### 7.1.3 Adverse device effect (ADE)

"Adverse event related to the use of an investigational medical device

NOTE 1 This definition includes adverse events resulting from insufficient or inadequate instructions for use, deployment, implantation, installation, or operation, or any malfunction of the investigational medical device.

NOTE 2 This definition includes any event resulting from an error use or from intentional misuse of the investigational medical device."

### 7.1.4 Serious adverse device effect (SADE)

Adverse device effect that has resulted in any of the consequences characteristic of a serious adverse event

### 7.1.5 Unanticipated serious adverse device effect (USADE)

"Serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report

NOTE Anticipated serious adverse device effect (ASADE) is an effect which by its nature, incidence, severity or outcome has been identified in the risk analysis report."

## 7.2 Documentation and reporting of adverse event by the investigator

All subjects who have adverse events, whether considered associated with the use of the implant or not, must be monitored to determine the outcome.

The following causal relationships will be assessed:

i) Event related to specific study device?
ii) Event related to surgery procedure?

This will be reported by the surgeon as:

- Yes*
- No
- Uncertain*

*If Yes or Uncertain, the Adverse Event form shall be sent to Stryker within 24 hours.

All serious adverse events, serious adverse device effects, adverse device effects and unexpected adverse events, in accordance with the above definitions, must be reported to the sponsor **within 24 hours** from their occurrence, using the *Stryker Clinical Adverse Event Report Form* (according to Stryker Clinical procedures). Subsequent follow-up reports will be provided to the sponsor.

A *Stryker Clinical Adverse Event Report Form* should be completed by the investigator and sent by email or fax **within 24 hours** to the sponsor either:

- local clinical contact by email or fax or
- Clinical Study Manager
  ntx.registry@stryker.com
  Phone: +49 2065 837-0

If at the time of sending the report, all details are not available by the investigator; the partially completed form must be sent with the available data and then the investigator will seek to obtain complementary information. The complementary information will be sent by the investigator to the sponsor as soon as it will be available.

In addition, all adverse events, serious or not, occurring between two planned visits will be reported in the CRF. Death will be both reported in the a*dverse event CRF* and in the *termination CRF pages*.

Moreover the investigator should send to the Sponsor a copy of the imaging exam when performed at the time of the adverse event, as part of the standard post-marketing vigilance system for the CE certified Stryker products. The investigator will evaluate the adverse event and determine the most appropriate actions.
The sponsor will report adverse events to Competent Authorities and Ethic Committees that occur in accordance with applicable regulations.

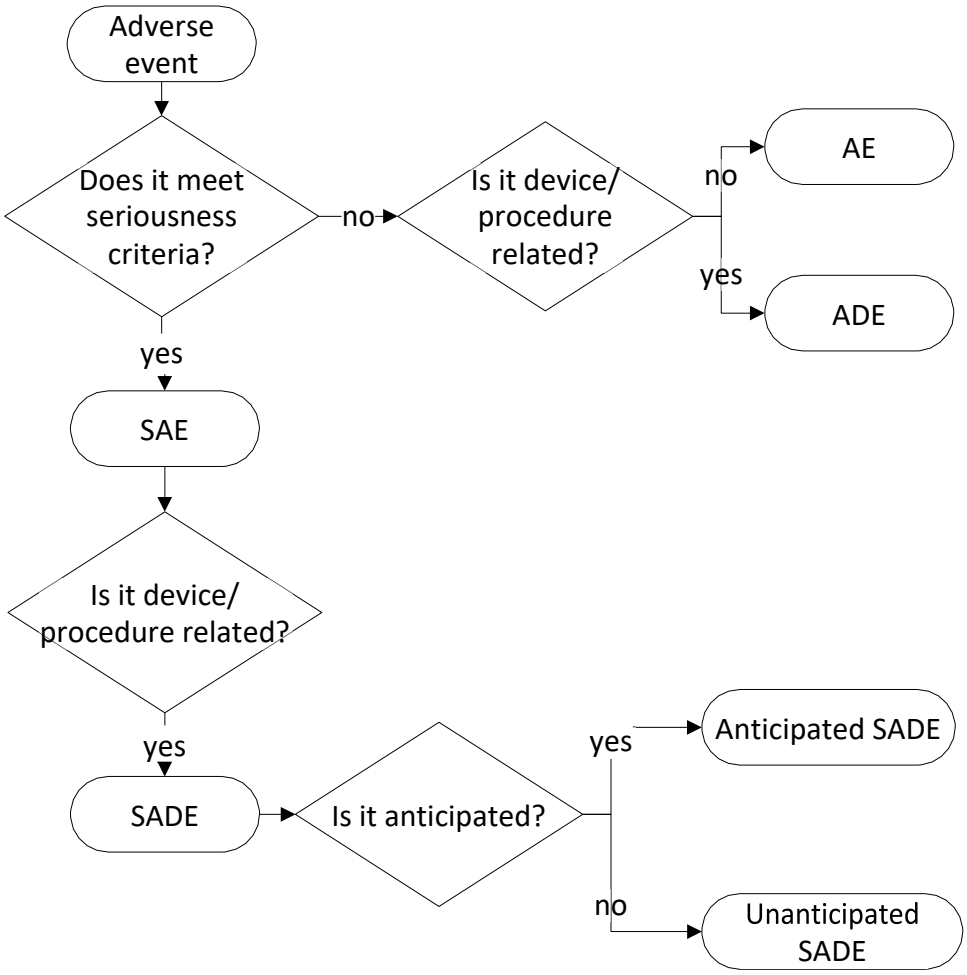


Figure: Adverse Events Categorization chart (from ISO 14155:2011)

# 8 PATIENT WITHDRAWALS

Patients are free to withdraw from the Surveillance at any time and are under no obligation to provide a reason for doing so. Patients who withdraw from the Surveillance should have the reason for their withdrawal recorded on the termination case report forms (CRF's), if at all possible. All attempts should be made to ascertain whether any patient apparently lost to follow up has actually chosen not to return or is deceased.

# 9 ELECTRONIC DATA CAPTURE: eCRF

All the above-mentioned pre-operative patient assessments, intra-operative details and post-operative follow-up assessments will be recorded on a CRF (Case Report Forms) which will be provided to any centre being part of the NTX Registry.

The CRF will be provided electronically (secured electronic data capture: EDC). A patient blank paper case report form can be printed by surgeons wishing data collection on paper before data entry in the EDC. After EDC data entry, a hard copy can be printed as well for

each patient by the surgeon(s). The EDC system complies with the FDA and international requirements for electronic database(s) security and performances.

The system will be secured to prevent unauthorized access to the data or to the system by using the combination of user ID and password which will be provided by Stryker SA to the authorised users of each centre. The investigator will maintain a list of individuals who are authorized to enter or correct data in the system.

The surgeon and his/her other defined users will receive system documentation, training and support for the use of the EDC. All required information collected during the following period must be entered by the investigator or designated representative in the EDC. All data entry, modification or deletion will be recorded automatically in an electronic audit trail (tracking of the data entered or modified). The combination of both user ID and password will correspond to the surgeon electronic signature which will be required for patient data validation.

The secured database will be physically hosted by Stryker Orthopaedics Mahwah, New Jersey (US).

The upmost best will be done to maintain confidentiality and anonymity at all times by use of the unique registry patient ID code. Only this patient ID code (no patient names, addresses, hospital numbers) will be recorded in the database.

# 10 SURVEILLANCE MONITORING

During the course of the Stryker NTX Registry and thereafter until the centre has been closed, the monitor(s) possibly visit the Centre(s) recruiting patients into the Registry by prior arrangement. The following persons can be contacted at any time concerning any problems or queries.

- local clinical contact by email or fax
  or
- Clinical Study Manager
  ntx.registry@stryker.com
  Phone: +49 2065 837-0

The monitor shall be given unhindered access to monitor relevant source documents (including medical records) to enable complete data verification, but with respect to the patient's integrity as described in section 14.4.

# 11 ANALYSIS OF RESULTS AND REPORTS

Results obtained from the NTX Registry will be tabulated and statistically analysed by Stryker's Clinical Department using an appropriate statistical software package. An interim analysis of the data will be made once appropriate patients are included in the Outcomes Registry.

There will be 2 types of annual reports on register data. i) Stryker Clinical will prepare a report on the overall dataset ii) each Investigator will receive a confidential report from data from their own institute including benchmarks relative to the average without disclosure of the results of other departments.

Possible analyses of the data include:

- **Safety** during follow-up and **Survivorship** as described by Kaplan-Meier survival curves:
  - Adverse events: All intra-operative and post-operative adverse events will be recorded.
  - Survivorship with regard to the revision of the entire system or system components (e.g. insert only, tibia base plate only)
  - Survivorship with regard to re-operation without component exchange

- **Patient clinical outcome**
  - Standard clinical parameters and KSS (Knee Society Score) as well as patient questionnaires (EQ5D (EuroQol Group) and KOOS (Knee Injury and Osteoarthritis Outcome Score)) preoperatively and each follow-up visit.

## 11.1 Statistical Methodology

The patient's safety and survivorship of the implants during the follow-ups will be described by Kaplan-Meier survival curves:

- Survivorship with regard to the revision of the entire system or system components (e.g. insert only, tibia base plate only)
- Survivorship with regard to re-operation without component exchange
- all other adverse events types can be separately considered as failures for Kaplan-Meier survival curve assessment.

In addition to the Kaplan Meier survival curves, the surgeons involved in the register will have the possibility to analyse the following statistical descriptions/comparisons:

- Demographic and pre-operative assessments
- Intra-operative assessments
- KSS (pain/motion score, function score).
- Patient questionnaires: KOOS, EQ5D Quality of Life assessment
- Adverse events and device-related adverse events
- Revisions/removals

Frequency and percent distributions will be presented in tabular form for categorical variables. The mean, standard deviation, minimum and maximum values will be presented for quantitative variables.

# 12 PUBLICATION OF RESULTS

By signing the Clinical Contract, the investigator agrees to the results of the outcomes registry being used for publication and for informing medical professionals. If necessary, names, addresses, qualifications and the role of the investigator in the outcomes registry shall be notified to the authorities.

The sponsor shall compile a final outcomes report.

The co-ordinating investigator and the principal investigators at each centre must confirm, by their signature, that they have read the report. They must confirm that to their knowledge, the report describes the outcomes results, and the way in which it has been conducted, accurately.

The method and timetable for compiling the publications shall be defined by mutual agreement between the Sponsor and the Investigators.

# 13 RISK BENEFIT ANALYSIS

## 13.1 Risk

There is no additional risk associated in participating in this outcomes register over and above that of the primary knee total arthroplasty or partial knee resurfacing (unicompartmental knee) procedure.

As in any surgical procedure, certain risks are associated with joint arthroplasty. These risks include but are not limited to: anaesthetic and post-anaesthetic reactions (such as hyperaemia), allergic reactions to prophylactic antibiotics or blood transfusions, damage to blood vessels or nerves, trochanteric or femoral fractures during implantation, perforation of the cortical wall, or death. Post-operatively, a patient may experience thrombophlebitis, pulmonary embolus, dislocation, pain, limp, component loosening, osteolysis due to wear debris or the need for additional surgery. Fracture of the prosthesis is a potential complication.

Adverse Events may necessitate re-operation, revision, arthrodesis of the involved joint, girdlestone or amputation of the limb.

## 13.2 Minimization of Risks

All components of the Scorpio NRG Total Knee System (with CR and PS insert), Triathlon Total Knee System (with CR and PS insert and CS insert) as well as the Triathlon Partial Knee Resurfacing System (Triathlon PKR) used in this post-market clinical registry have been CE marked (CE0086) according to the Medical Device Directive 93/42/EEC and therefore are approved for sale on the European market.

Pre-clinical, clinical, and mechanical testing of the above listed implants indicate that the above mentioned risks should not occur at a rate greater than that for any other type of knee arthroplasty reported in the literature.

Patients will be treated in the best medical judgement of the investigator, regardless of the outcomes registry.

### 13.3 Benefit

Patient benefits should include relief of pain and increase in functional capabilities, in addition to better assessment of the effect of prosthesis design and materials on functional and radiographic performance and bone remodelling around knee prostheses. This will increase the current scientific body of knowledge concerning total and unicompartmental knee arthroplasty.

## 14 ETHICAL CONSIDERATIONS

### 14.1 Declaration of Helsinki

The Surveillance will follow the guidelines as laid down by the "Declaration of Helsinki" (Declaration of Helsinki, October 2008) (**APPENDIX I -** DECLARATION OF HELSINKI).

In accordance with the Declaration of Helsinki, where applicable, all centres will gain written Ethics Committee approval prior to enrolling patients in the Surveillance either from the local responsible Ethics Committee at the investigator site or from an adequately constituted (according to ISO14155: 2011) independent Ethics Committee.

If a full Ethic Committee approval is not required, then a written confirmation of this is required from the responsible EC stating that data can be collected from that particular site.

### 14.2 Informed Consent

All recruited patients will sign and date the informed consent form before any investigational procedure or visit is performed. Only the latest ethics committee approved version is a valid document. The patient is provided with a copy of the information letter and consent form. The investigator is acquainted with the contents of the information sheet and answers patient questions regarding participation in the outcomes registry.

### 14.3 Patient Insurance (product liability)

Participating patients in this Surveillance are covered by Stryker SA product liability insurance.

## 14.4 Personal data protection

Stryker SA affirms and upholds the principle of the patient rights to protection against invasion of privacy. All data recorded in the CRFs or used for further evaluation are coded by patient number and age. Identification is restricted to authorized persons. In all data analyses the identity of patients will remain anonymous. Anonymous patient data may be stored and electronically processed by Stryker Clinical for the purpose of scientific evaluation and may be forwarded to a company and/or an authority located in- and outside Europe for registration and/or marketing purposes. Only authorized representatives of Stryker Clinical and health authorities will have allowed access to personal medical records for the sole purpose of checking the accuracy of data collected in the registry.

# 15 GLOSSARY

**A**

| | |
|---|---|
| ASA | American Society of Anaesthesiology scoring system for grading the overall physical condition of the patient, as follows: P1 – fit and healthy; P2 – mild disease, not incapacitating; P3 – incapacitating systemic disease; P4 – life threatening disease; P5 – not expected to survive 24 hours. |

**B**

| | |
|---|---|
| Bilateral operation | Operation performed on both sides, e.g. left and right knee procedures carried out during a single operation. |
| BMI | Body mass index. A statistical tool used to estimate a healthy body weight based on an individual's height. The BMI is calculated by dividing a person's weight (kg) by the square of their height ($m^2$). |

**C**

| | |
|---|---|
| Case mix | Term used to describe variation in surgical practice, relating to factors such as indications for surgery, patient age and sex. |
| Cement | The material used to fix cemented joint replacements to bone - polymethyl methacrylate (PMMA). |
| Cemented | Prostheses designed to be fixed into the bone using cement. |
| Cementless | Prostheses designed to be fixed into the bone by bony ingrowth or ongrowth, without using cement. |
| CI | A confidence interval (CI) gives an estimated range of values which is likely to include the unknown population parameter (e.g. a revision rate) being estimated from the given sample. If independent samples are taken repeatedly from the same population, and a confidence interval calculated for each sample, then a certain percentage (confidence level: e.g. 95%) of the intervals will include the unknown population parameter. |

**E**

| | |
|---|---|
| EQ-5D | EQ-5D is a standardised measure of health status developed by the EuroQol Group in order to provide a simple, generic measure of health for clinical and economic appraisal. The EQ-5D descriptive system comprises the following 5 |

| | |
|---|---|
| | dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. |
| **F** | |
| Femoral component (knee) | Portion of a knee prosthesis that is used to replace the articulating surface of the femur (thigh bone). |
| **H** | |
| HA | hydroxyapatite |
| Hazard ratio | A comparative statistical measure of the instantaneous risk of experiencing the event of interest (e.g. implant revision) between two groups (e.g. two different products). |
| Hybrid procedure | Joint replacement procedure in which cement is used to fix one prosthetic component while the other is cementless. |
| **I** | |
| Image/computer guided surgery | Surgery performed by the surgeon, using real time images to assist alignment and positioning of prosthetic components |
| Indication (for surgery) | The reason for surgery. |
| **K** | |
| Kaplan-Meier | A statistical method of carrying out a survivorship analysis that can take into account 'censored' data, i.e. patient losses from the sample before the final outcome is observed (for instance, if a patient dies). |
| KOOS | Knee Injury and Osteoarthritis Outcome Score |
| KSS | Knee Society Score |
| **O** | |
| Outlier | Data for a surgeon, unit or implant brand that falls outside of the defined control limits. |
| **P** | |
| PA | Peri-Apatite |
| Patella resurfacing | Replacement of the surface of the patella (knee cap) with a prosthesis. |
| Patient consent | A patient can only be included in the Stryker Clinical Registry where explicit informed patient consent has been given. |
| Patient physical status | See ASA. |
| PKR | Partial Knee Resurfacing (Unicompartmental knee, UKA) |
| Primary knee replacement | First total joint replacement operation performed on any individual patient. |
| Prosthesis | Orthopaedic implant used in joint replacement procedures, e.g. a total hip or a unicondylar knee. |
| p-value | A p-value is reported as a result of a statistical hypothesis test. It represents the probability that any observed differences are due to chance. If the p-value is below a pre-determined cut-off (traditionally 0.05) the result is called "statistically significant" and it can be concluded that the observed differences are unlikely to be due to chance. |

**R**

| | |
|---|---|
| Revision knee replacement | Operation performed to remove and replace one or more components of a total joint prosthesis for whatever reason. |

**S**

| | |
|---|---|
| Standard Deviation (SD) | The standard deviation is a measure of the spread of the data about the average. The smaller the standard deviation, the less spread out the data. |
| Surgical approach | Method used by a surgeon to gain access to, and expose, the joint. |
| Survivorship analysis | A statistical method that is used to determine what fraction of a population, such as those who have had a particular hip implant, has survived unrevised past a certain time. See Kaplan-Meier. |

**T**

| | |
|---|---|
| Thromboprophylaxis | Drug or other post-operative regime prescribed to patients with the aim of preventing blood clot formation in the post-operative period. |
| THA | Total hip arthroplasty. |
| TKA | Total knee arthroplasty (total knee replacement). Replacement of both tibial and both femoral condyles, with or without resurfacing of the patella and with or without cement. |
| Total condylar knee | Type of knee prosthesis that replaces the complete contact area between the femur and the tibia of a patient's knee. |
| Trochanter | Bony protuberance of the femur, found on its upper outer aspect. |
| Type (of prosthesis) | Type of prosthesis is the generic description of a prosthesis, e.g. modular cemented stem (hip), patello-femoral joint (knee). |

**U**

| | |
|---|---|
| Uncemented | See cementless. |
| Unicondylar arthroplasty | Replacement of one tibial condyle and one femoral condyle in the knee, with or without resurfacing of the patella. |
| Unicondylar knee replacement | See Unicondylar arthroplasty. |
| Unilateral operation | Operation performed on one side only, e.g. left knee. |

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# APPENDIX I - DECLARATION OF HELSINKI

## DECLARATION OF HELSINKI WORLD MEDICAL ASSOCIATION (DoH 2008)

### Ethical Principles for Medical Research Involving Human Subjects

Adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and amended by the:
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
52nd WMA General Assembly, Edinburgh, Scotland, October 2000
53th WMA General Assembly, Washington 2002 (Note of Clarification on paragraph 29 added)
55th WMA General Assembly, Tokyo 2004 (Note of Clarification on Paragraph 30 added)
59th WMA General Assembly, Seoul, October 2008

#### A. INTRODUCTION

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects**,** including research on identifiable human material and data.
The Declaration is intended to be read as a whole and each of its constituent paragraphs should not be applied without consideration of all other relevant paragraphs.

2. Although the Declaration is addressed primarily to physicians, the WMA encourages other participants in medical research involving human subjects to adopt these principles.

3. It is the duty of the physician to promote and safeguard the health of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.

4. The Declaration of Geneva of the WMA binds the physician with the words, “The health of my patient will be my first consideration,” and the International Code of Medical Ethics declares that, “A physician shall act in the patient's best interest when providing medical care.”

5. Medical progress is based on research that ultimately must include studies involving human subjects. Populations that are underrepresented in medical research should be provided appropriate access to participation in research.

6. In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests.

7. The primary purpose of medical research involving human subjects is to understand the causes, development and effects of diseases and improve preventive, diagnostic and therapeutic interventions (methods, procedures and treatments). Even the best current interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility and quality.

8. In medical practice and in medical research, most interventions involve risks and burdens.

9. Medical research is subject to ethical standards that promote respect for all human subjects and protect their health and rights. Some research populations are particularly vulnerable and need special protection. These include those who cannot give or refuse consent for themselves and those who may be vulnerable to coercion or undue influence.

10. Physicians should consider the ethical, legal and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.

**B. PRINCIPLES FOR ALL MEDICAL RESEARCH**

11. It is the duty of physicians who participate in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects.

12. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.

13. Appropriate caution must be exercised in the conduct of medical research that may harm the environment.

14. The design and performance of each research register involving human subjects must be clearly described in a research protocol. The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding, sponsors, institutional affiliations, other potential conflicts of interest, incentives for subjects and provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research register. The protocol should describe arrangements for post-register access by register subjects to interventions identified as beneficial in the register or access to other appropriate care or benefits.

15. The research protocol must be submitted for consideration, comment, guidance and approval to a research ethics committee before the register begins. This committee must be independent of the researcher, the sponsor and any other undue influence. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration. The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No change to the protocol may be made without consideration and approval by the committee.

16. Medical research involving human subjects must be conducted only by individuals with the appropriate scientific training and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other health care professional. The responsibility for the protection of research subjects must always rest with the physician or other health care professional and never the research subjects, even though they have given consent.

17. Medical research involving a disadvantaged or vulnerable population or community is only justified if the research is responsive to the health needs and priorities of this population or community and if there is a reasonable likelihood that this population or community stands to benefit from the results of the research.

18. Every medical research register involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and communities involved in the research in comparison with foreseeable benefits to them and to other individuals or communities affected by the condition under investigation.

19. Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject.

20. Physicians may not participate in a research register involving human subjects unless they are confident that the risks involved have been adequately assessed and can be satisfactorily managed. Physicians must immediately stop a register when the risks are found to outweigh the potential benefits or when there is conclusive proof of positive and beneficial results.

21. Medical research involving human subjects may only be conducted if the importance of the objective outweighs the inherent risks and burdens to the research subjects.

22. Participation by competent individuals as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no competent individual may be enrolled in a research register unless he or she freely agrees.

23. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information and to minimize the impact of the register on their physical, mental and social integrity.

24. In medical research involving competent human subjects, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the register and the discomfort it may entail, and any other relevant aspects of the register. The potential subject must be informed of the right to refuse to participate in the register or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information. After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-written consent must be formally documented and witnessed.

25. For medical research using identifiable human material or data, physicians must normally seek consent for the collection, analysis, storage and/or reuse. There may be situations where consent would be impossible or impractical to obtain for such research or would pose a threat to the validity of the research. In such situations the research may be done only after consideration and approval of a research ethics committee.

26. When seeking informed consent for participation in a research register the physician should be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent should be sought by an appropriately qualified individual who is completely independent of this relationship.

27. For a potential research subject who is incompetent, the physician must seek informed consent from the legally authorized representative. These individuals must not be included in a research register that has no likelihood of benefit for them unless it is intended to promote the health of the population represented by the potential subject, the research cannot instead be performed with competent persons, and the research entails only minimal risk and minimal burden.

28. When a potential research subject who is deemed incompetent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject's dissent should be respected.

29. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research population. In such circumstances the physician should seek informed consent from the legally authorized representative. If no such representative is available and if the research cannot be delayed, the register may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the register has been approved by a research ethics committee. Consent to remain in the research should be obtained as soon as possible from the subject or a legally authorized representative.

30. Authors, editors and publishers all have ethical obligations with regard to the publication of the results of research. Authors have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. They should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results should be published or otherwise made publicly available. Sources of funding, institutional affiliations and conflicts of interest should be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

## C. ADDITIONAL PRINCIPLES FOR MEDICAL RESEARCH COMBINED WITH MEDICAL CARE

31. The physician may combine medical research with medical care only to the extent that

the research is justified by its potential preventive, diagnostic or therapeutic value and if the physician has good reason to believe that participation in the research register will not adversely affect the health of the patients who serve as research subjects.

32. The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstances:
• The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists; or
• Where for compelling and scientifically sound methodological reasons the use of placebo is necessary to determine the efficacy or safety of an intervention and the patients who receive placebo or no treatment will not be subject to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option.

33. At the conclusion of the register, patients entered into the register are entitled to be informed about the outcome of the register and to share any benefits that result from it, for example, access to interventions identified as beneficial in the register or to other appropriate care or benefits.

34. The physician must fully inform the patient which aspects of the care are related to the research. The refusal of a patient to participate in a register or the patient's decision to withdraw from the register must never interfere with the patient-physician relationship.

35. In the treatment of a patient, where proven interventions do not exist or have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven intervention if in the physician's judgement it offers hope of saving life, re-establishing health or alleviating suffering. Where possible, this intervention should be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information should be recorded and, where appropriate, made publicly available.

## APPENDIX II - PATIENT INFORMATION SHEET AND INFORMED CONSENT

PLEASE NOTE: This is a template document and may need to be adapted to meet local Ethical Committee requirements.

# PATIENT INFORMATION SHEET AND INFORMED CONSENT

## Stryker NTX Registry

My surgeon informed me that he/she is participating in collaboration with Stryker SA, the manufacturer of my knee prosthesis, in a surveillance register of the type of knee implant I will be receiving, in order to document the long term safety and survivorship of these implants. I've understood that many patients from different European hospitals/clinics will freely take part in this register.

I also understood that the clinical visits for this register are considered to be within the scope of normal clinical practice required for the follow-up of my knee in the hospital/clinic where I will be operated. It is anticipated that data will be collected before and during surgery, as well as follow-up visits up to 10 years after surgery. There are also two patient questionnaires to be filled-out at each of these visits. No additional x-rays will be performed for the registry.

I agree that Stryker SA, the manufacturer of my new knee, receives my anonymous coded clinical information which is related to my new knee. I understand that the knee implant, that I am going to receive, has continuously been developed and improved over the last years and that my clinical data, together with the data from other patients taking part in this registry study, will be used to confirm the safety and efficacy of the implant.

I understand that my clinical data collected during the surveillance register is recorded electronically in a secured database and also possibly on paper, this data may be stored and electronically processed by Stryker SA for the purpose of scientific evaluation and may be forwarded to a company and/or an authority located in and outside Europe for registration and/or marketing purposes (the attachment to the patient information – is the legal description of the extent of data protection, which is a requirement of the implant

manufacturer to include). Only authorized representatives of Stryker SA and health authorities will have allowed access to personal medical records for the sole purpose of checking the accuracy of data collected in the knee register.

I agree that my clinical information is possibly used for publications and that I will never be recognized in such a publication.

I understand that my participation is voluntary and that at any time I can refuse that new information will be recorded without affecting the received quality of care.

Patient name ……..

Signature …… Date …….

Surgeon name …….

Signature …… Date …….

**OPTIONAL**
Witness name (optional) …….

Signature …… Date …….
Relative/ Representative/Other

**Attachment to Patient Information**
This research will involve the collection of data, perhaps including personal information. These data may be held by Stryker or subsidiaries of Stryker. By consenting to the research I agree that Stryker may, if appropriate for scientific purposes, transfer data both internally (common ownership with Stryker) and externally (contracted third parties). If data is conveyed to a third party outside EU / EEA the receiving party must comply with the data protection laws of Switzerland, a country for which the European Commission considers data protection laws to be adequate. This consent can be withdrawn at any time without influence on the contract governing your place in the clinical trial.

## APPENDIX III - PRODUCT COMPONENT SIZES

# 1. Scorpio NRG Total Knee System

## 1.1. Femoral Components

### 1.1.1. Cemented

- **NRG CR**

| | |
|---|---|
| 80-4403L | SCP NRG Fem CR # 3 left, cemented |
| 80-4403R | SCP NRG Fem CR # 3 right, cemented |
| 80-4404L | SCP NRG Fem CR # 4 left, cemented |
| 80-4404R | SCP NRG Fem CR # 4 right, cemented |
| 80-4405L | SCP NRG Fem CR # 5 left, cemented |
| 80-4405R | SCP NRG Fem CR # 5 right, cemented |
| 80-4406L | SCP NRG Fem CR # 6 left, cemented |
| 80-4406R | SCP NRG Fem CR # 6 right, cemented |
| 80-4407L | SCP NRG Fem CR # 7 left, cemented |
| 80-4407R | SCP NRG Fem CR # 7 right, cemented |
| 80-4408L | SCP NRG Fem CR # 8 left, cemented |
| 80-4408R | SCP NRG Fem CR # 8 right, cemented |
| 80-4409L | SCP NRG Fem CR # 9 left, cemented |
| 80-4409R | SCP NRG Fem CR # 9 right, cemented |
| 80-4411L | SCP NRG Fem CR # 11 left, cemented |
| 80-4411R | SCP NRG Fem CR # 11 right, cemented |
| 80-4413L | SCP NRG Fem CR # 13 left, cemented |
| 80-4413R | SCP NRG Fem CR # 13 right, cemented |



- **NRG PS**

| | |
|---|---|
| 81-4403L | SCP NRG Fem PS # 3 left, cemented with Pegs |
| 81-4403R | SCP NRG Fem PS # 3 right, cemented with Pegs |
| 81-4404L | SCP NRG Fem PS # 4 left, cemented with Pegs |
| 81-4404R | SCP NRG Fem PS # 4 right, cemented with Pegs |
| 81-4405L | SCP NRG Fem PS Waffel # 5 left, cemented with Pegs |
| 81-4405R | SCP NRG Fem PS Waffel # 5 right, cemented with Pegs |
| 81-4406L | SCP NRG Fem PS # 6 left, cemented with Pegs |
| 81-4406R | SCP NRG Fem PS # 6 right, cemented with Pegs |
| 81-4407L | SCP NRG Fem PS Waffel # 7 left, cemented with Pegs |
| 81-4407R | SCP NRG Fem PS Waffel # 7 right, cemented with Pegs |
| 81-4408L | SCP NRG Fem PS # 8 left, cemented with Pegs |
| 81-4408R | SCP NRG Fem PS # 8 right, cemented with Pegs |
| 81-4409L | SCP NRG Fem PS Waffel # 9 left, cemented with Pegs |
| 81-4409R | SCP NRG Fem PS Waffel # 9 right, cemented with Pegs |
| 81-4411L | SCP NRG Fem PS Waffel # 11 left, cemented with Pegs |
| 81-4411R | SCP NRG Fem PS Waffel # 11 right, cemented with Pegs |
| 81-4413L | SCP NRG Fem PS Waffel # 13 left, cemented with Pegs |
| 81-4413R | SCP NRG Fem PS Waffel # 13 right, cemented with Pegs |

### 1.1.2. Cementless

- **NRG CR**

| | |
|---|---|
| 80-6403L | SCP NRG HA CR Fem #3 L |
| 80-6403R | SCP NRG HA CR Fem #3 R |
| 80-6404L | SCP NRG HA CR Fem #4 L |
| 80-6404R | SCP NRG HA CR Fem #4 R |
| 80-6405L | SCP NRG HA CR Fem #5 L |
| 80-6405R | SCP NRG HA CR Fem #5 R |
| 80-6406L | SCP NRG HA CR Fem #6 L |
| 80-6406R | SCP NRG HA CR Fem #6 R |
| 80-6407L | SCP NRG HA CR Fem #7 L |
| 80-6407R | SCP NRG HA CR Fem #7 R |
| 80-6408L | SCP NRG HA CR Fem #8 L |
| 80-6408R | SCP NRG HA CR Fem #8 R |
| 80-6409L | SCP NRG HA CR Fem #9 L |
| 80-6409R | SCP NRG HA CR Fem #9 R |
| 80-6411L | SCP NRG HA CR Fem #11 L |
| 80-6411R | SCP NRG HA CR Fem #11 R |
| 80-6413L | SCP NRG HA CR Fem #13 L |
| 80-6413R | SCP NRG HA CR Fem #13 R |

- **NRG PS**

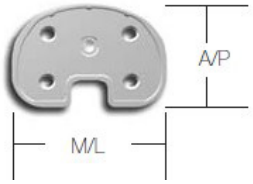
| | |
|---|---|
| 81-6403L | SCP NRG HA PS Fem #3 L |
| 81-6403R | SCP NRG HA PS Fem #3 R |
| 81-6404L | SCP NRG HA PS Fem #4 L |
| 81-6404R | SCP NRG HA PS Fem #4 R |
| 81-6405L | SCP NRG HA PS Fem #5 L |
| 81-6405R | SCP NRG HA PS Fem #5 R |
| 81-6406L | SCP NRG HA PS Fem #6 L |
| 81-6406R | SCP NRG HA PS Fem #6 R |
| 81-6407L | SCP NRG HA PS Fem #7 L |
| 81-6407R | SCP NRG HA PS Fem #7 R |
| 81-6408L | SCP NRG HA PS Fem #8 L |
| 81-6408R | SCP NRG HA PS Fem #8 R |
| 81-6409L | SCP NRG HA PS Fem #9 L |
| 81-6409R | SCP NRG HA PS Fem #9 R |
| 81-6411L | SCP NRG HA PS Fem #11 L |
| 81-6411R | SCP NRG HA PS Fem #11 R |
| 81-6413L | SCP NRG HA PS Fem #13 L |
| 81-6413R | SCP NRG HA PS Fem #13 R |

## 1.2. Tibia Component

### 1.2.1. Cemented

- **Scorpio® Primary Knee System Tibial Baseplate**


| | |
|---|---|
| 7115-0003 | SCP Tibia Waffel # 3 cemented |
| 7115-0004 | SCP Tibia Waffel # 4 cemented |
| 7115-0005 | SCP Tibia Waffel # 5 cemented |
| 7115-0006 | SCP Tibia Waffel # 6 cemented |
| 7115-0007 | SCP Tibia Waffel # 7 cemented |
| 7115-0009 | SCP Tibia Waffel # 9 cemented |
| 7115-0011 | SCP Tibia Waffel # 11 cemented |
| 7115-0013 | SCP Tibia Waffel # 13 cemented |




### 1.2.2. Cementless

- **Scorpio® Primary Knee System Tibial Baseplate**

| | |
|---|---|
| 75150003 | SCP TIB HA cementless #3 |
| 75150005 | SCP TIB HA cementless #5 |
| 75150006 | SCP TIB HA cementless #6 |
| 75150007 | SCP TIB HA cementless #7 |
| 75150009 | SCP TIB HA cementless #9 |
| 75150011 | SCP TIB HA cementless #11 |

| | |
|---|---|
| 7125-0003 | SCP Tibia beaded # 3, cementless |
| 7125-0004 | SCP Tibia beaded #4 cementless |
| 7125-0005 | SCP Tibia beaded # 5, cementless |
| 7125-0006 | SCP Tibia beaded #6 cementless |
| 7125-0007 | SCP Tibia beaded # 7, cementless |
| 7125-0009 | SCP Tibia beaded # 9, cementless |
| 7125-0011 | SCP Tibia beaded # 11, cementless |
| 7125-0013 | SCP Tibia beaded # 13, cementless |

| | |
|---|---|
| 7145-0003 | SCP Tibia beaded PA #3 cementless |
| 7145-0005 | SCP Tibia beaded PA #5 cementless |
| 7145-0007 | SCP Tibia beaded PA #7 cementless |
| 7145-0009 | SCP Tibia beaded PA #9 cementless |
| 7145-0011 | SCP Tibia beaded PA #11 cementless |
| 7145-0013 | SCP Tibia beaded PA #13 cementless |

## 1.3. Insert

- **CR**

| | |
|---|---|
| 82-6-0308 | SCP NRG Tib Ins CR X3 #3 Thickness 8mm |
| 82-6-0310 | SCP NRG Tib Ins CR X3 #3 Thickness 10mm |
| 82-6-0312 | SCP NRG Tib Ins CR X3 #3 Thickness 12mm |
| 82-6-0315 | SCP NRG Tib Ins CR X3 #3 Thickness 15mm |
| 82-6-0318 | SCP NRG Tib Ins CR X3 #3 Thickness 18mm |

| | |
|---|---|
| 82-6-0321 | SCP NRG Tib Ins CR X3 #3 Thickness 21mm |
| 82-6-0324 | SCP NRG Tib Ins CR X3 #3 Thickness 24mm |
| 82-6-0508 | SCP NRG Tib Ins CR X3 #5 Thickness 8mm |
| 82-6-0510 | SCP NRG Tib Ins CR X3 #5 Thickness 10mm |
| 82-6-0512 | SCP NRG Tib Ins CR X3 #5 Thickness 12mm |
| 82-6-0515 | SCP NRG Tib Ins CR X3 #5 Thickness 15mm |
| 82-6-0518 | SCP NRG Tib Ins CR X3 #5 Thickness 18mm |
| 82-6-0521 | SCP NRG Tib Ins CR X3 #5 Thickness 21mm |
| 82-6-0524 | SCP NRG Tib Ins CR X3 #5 Thickness 24mm |
| 82-6-0708 | SCP NRG Tib Ins CR X3 #7 Thickness 8mm |
| 82-6-0710 | SCP NRG Tib Ins CR X3 #7 Thickness 10mm |
| 82-6-0712 | SCP NRG Tib Ins CR X3 #7 Thickness 12mm |
| 82-6-0715 | SCP NRG Tib Ins CR X3 #7 Thickness 15mm |
| 82-6-0718 | SCP NRG Tib Ins CR X3 #7 Thickness 18mm |
| 82-6-0721 | SCP NRG Tib Ins CR X3 #7 Thickness 21mm |
| 82-6-0724 | SCP NRG Tib Ins CR X3 #7 Thickness 24mm |
| 82-6-0908 | SCP NRG Tib Ins CR X3 #9 Thickness 8mm |
| 82-6-0910 | SCP NRG Tib Ins CR X3 #9 Thickness 10mm |
| 82-6-0912 | SCP NRG Tib Ins CR X3 #9 Thickness 12mm |
| 82-6-0915 | SCP NRG Tib Ins CR X3 #9 Thickness 15mm |
| 82-6-0918 | SCP NRG Tib Ins CR X3 #9 Thickness 18mm |
| 82-6-0921 | SCP NRG Tib Ins CR X3 #9 Thickness 21mm |
| 82-6-0924 | SCP NRG Tib Ins CR X3 #9 Thickness 24mm |
| 82-6-1108 | SCP NRG Tib Ins CR X3 #11 Thickness 8mm |
| 82-6-1110 | SCP NRG Tib Ins CR X3 #11 Thickness 10mm |
| 82-6-1112 | SCP NRG Tib Ins CR X3 #11 Thickness 12mm |
| 82-6-1115 | SCP NRG Tib Ins CR X3 #11 Thickness 15mm |
| 82-6-1118 | SCP NRG Tib Ins CR X3 #11 Thickness 18mm |
| 82-6-1121 | SCP NRG Tib Ins CR X3 #11 Thickness 21mm |
| 82-6-1124 | SCP NRG Tib Ins CR X3 #11 Thickness 24mm |

- **PS**

| | |
|---|---|
| 82-7-0308 | SCP NRG Tib Ins PS X3 #3 Thickness 8mm |
| 82-7-0310 | SCP NRG Tib Ins PS X3 #3 Thickness 10mm |
| 82-7-0312 | SCP NRG Tib Ins PS X3 #3 Thickness 12mm |
| 82-7-0315 | SCP NRG Tib Ins PS X3 #3 Thickness 15mm |
| 82-7-0318 | SCP NRG Tib Ins PS X3 #3 Thickness 18mm |
| 82-7-0321 | SCP NRG Tib Ins PS X3 #3 Thickness 21mm |
| 82-7-0324 | SCP NRG Tib Ins PS X3 #3 Thickness 24mm |
| 82-7-0508 | SCP NRG Tib Ins PS X3 #5 Thickness 8mm |
| 82-7-0510 | SCP NRG Tib Ins PS X3 #5 Thickness 10mm |
| 82-7-0512 | SCP NRG Tib Ins PS X3 #5 Thickness 12mm |
| 82-7-0515 | SCP NRG Tib Ins PS X3 #5 Thickness 15mm |

| | |
|---|---|
| 82-7-0518 | SCP NRG Tib Ins PS X3 #5 Thickness 18mm |
| 82-7-0521 | SCP NRG Tib Ins PS X3 #5 Thickness 21mm |
| 82-7-0524 | SCP NRG Tib Ins PS X3 #5 Thickness 24mm |
| 82-7-0708 | SCP NRG Tib Ins PS X3 #7 Thickness 8mm |
| 82-7-0710 | SCP NRG Tib Ins PS X3 #7 Thickness 10mm |
| 82-7-0712 | SCP NRG Tib Ins PS X3 #7 Thickness 12mm |
| 82-7-0715 | SCP NRG Tib Ins PS X3 #7 Thickness 15mm |
| 82-7-0718 | SCP NRG Tib Ins PS X3 #7 Thickness 18mm |
| 82-7-0721 | SCP NRG Tib Ins PS X3 #7 Thickness 21mm |
| 82-7-0724 | SCP NRG Tib Ins PS X3 #7 Thickness 24mm |
| 82-7-0908 | SCP NRG Tib Ins PS X3 #9 Thickness 8mm |
| 82-7-0910 | SCP NRG Tib Ins PS X3 #9 Thickness 10mm |
| 82-7-0912 | SCP NRG Tib Ins PS X3 #9 Thickness 12mm |
| 82-7-0915 | SCP NRG Tib Ins PS X3 #9 Thickness 15mm |
| 82-7-0918 | SCP NRG Tib Ins PS X3 #9 Thickness 18mm |
| 82-7-0921 | SCP NRG Tib Ins PS X3 #9 Thickness 21mm |
| 82-7-0924 | SCP NRG Tib Ins PS X3 #9 Thickness 24mm |
| 82-7-1108 | SCP NRG Tib Ins PS X3 #11 Thickness 8mm |
| 82-7-1110 | SCP NRG Tib Ins PS X3 #11 Thickness 10mm |
| 82-7-1112 | SCP NRG Tib Ins PS X3 #11 Thickness 12mm |
| 82-7-1115 | SCP NRG Tib Ins PS X3 #11 Thickness 15mm |
| 82-7-1118 | SCP NRG Tib Ins PS X3 #11 Thickness 18mm |
| 82-7-1121 | SCP NRG Tib Ins PS X3 #11 Thickness 21mm |
| 82-7-1124 | SCP NRG Tib Ins PS X3 #11 Thickness 24mm |

## 1.4. Patella (optional)

| Medialized: | |
|---|---|
| 73-20-0110 | Scorpio X3 Patella #11 medialized Dome |
| 73-20-0510 | Scorpio X3 Patella # 5 medialized Dome |
| 73-20-0710 | Scorpio X3 Patella # 7 medialized Dome |
| 73-20-0910 | Scorpio X3 Patella # 9 medialized Dome |

| Concentric: | |
|---|---|
| 73-20-2510 | SCORPIO C-DOME X3 PATELLA #5-10mm |
| 73-20-2710 | SCORPIO C-DOME X3 PATELLA #7-10mm |
| 73-20-2910 | SCORPIO C-DOME X3 PATELLA #9-10mm |
| 73-20-2110 | SCORPIO C-DOME X3 PATELLA #11-10mm |

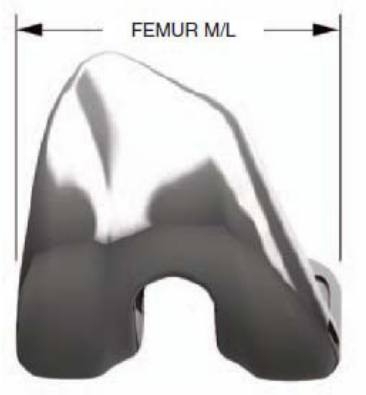
| Universal: | |
|---|---|
| 73-20-3308 | SCORPIO U-DOME X3 PATELLA #3-8mm |
| 73-20-3508 | SCORPIO U-DOME X3 PATELLA #5-8mm |
| 73-20-3708 | SCORPIO U-DOME X3 PATELLA #7-8mm |
| 73-20-3710 | SCORPIO U-DOME X3 PATELLA #7-10mm |
| 73-20-3910 | SCORPIO U-DOME X3 PATELLA #9-10mm |
| 73-20-3110 | SCORPIO U-DOME X3 PATELLA #11-10mm |

## 2. Triathlon Total Knee System

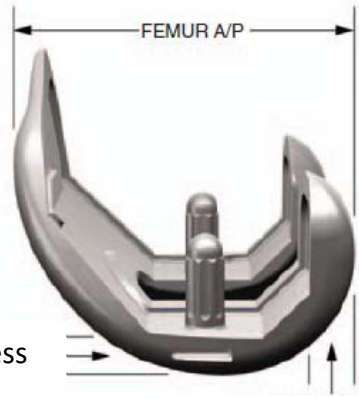
### 2.1. Femoral Components

#### 2.1.1. Cemented

- **Triathlon CR**




Component thickness

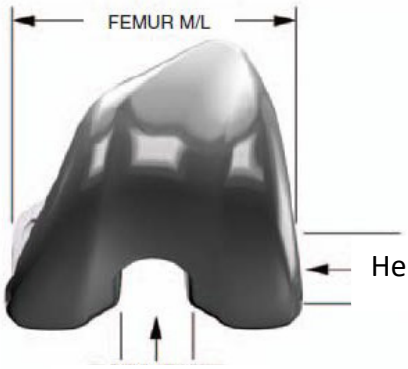



Component thickness

CR Femoral Component - Cemented Part Numbers

| | |
|---|---|
| 5510-F-101 | CR Femoral Component – Cemented #1 Left |
| 5510-F-102 | CR Femoral Component – Cemented #1 Right |
| 5510-F-201 | CR Femoral Component – Cemented #2 Left |
| 5510-F-202 | CR Femoral Component – Cemented #2 Right |
| 5510-F-301 | CR Femoral Component – Cemented #3 Left |
| 5510-F-302 | CR Femoral Component – Cemented #3 Right |
| 5510-F-401 | CR Femoral Component – Cemented #4 Left |
| 5510-F-402 | CR Femoral Component – Cemented #4 Right |
| 5510-F-501 | CR Femoral Component – Cemented #5 Left |
| 5510-F-502 | CR Femoral Component – Cemented #5 Right |
| 5510-F-601 | CR Femoral Component – Cemented #6 Left |
| 5510-F-602 | CR Femoral Component – Cemented #6 Right |
| 5510-F-701 | CR Femoral Component – Cemented #7 Left |
| 5510-F-702 | CR Femoral Component – Cemented #7 Right |
| 5510-F-801 | CR Femoral Component – Cemented #8 Left |
| 5510-F-802 | CR Femoral Component – Cemented #8 Right |

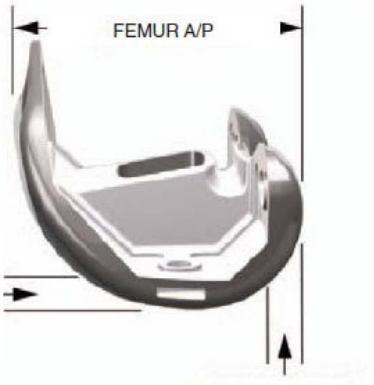
- **Triathlon PS**




Height of box

Width of box

Component thickness




Component thickness

**PS Femoral Component - Cemented Part Numbers**

| | |
|---|---|
| 5515-F-101 | PS Femoral Component – Cemented #1 Left |
| 5515-F-102 | PS Femoral Component – Cemented #1 Right |
| 5515-F-201 | PS Femoral Component – Cemented #2 Left |
| 5515-F-202 | PS Femoral Component – Cemented #2 Right |
| 5515-F-301 | PS Femoral Component – Cemented #3 Left |
| 5515-F-302 | PS Femoral Component – Cemented #3 Right |
| 5515-F-401 | PS Femoral Component – Cemented #4 Left |
| 5515-F-402 | PS Femoral Component – Cemented #4 Right |
| 5515-F-501 | PS Femoral Component – Cemented #5 Left |
| 5515-F-502 | PS Femoral Component – Cemented #5 Right |
| 5515-F-601 | PS Femoral Component – Cemented #6 Left |
| 5515-F-602 | PS Femoral Component – Cemented #6 Right |
| 5515-F-701 | PS Femoral Component – Cemented #7 Left |
| 5515-F-702 | PS Femoral Component – Cemented #7 Right |
| 5515-F-801 | PS Femoral Component – Cemented #8 Left |
| 5515-F-802 | PS Femoral Component – Cemented #8 Right |

### 2.1.2. Cementless

- **Triathlon CR**

**CR Femoral Cementless Component - Beaded Part Numbers**

| | |
|---|---|
| 5513-F-101 | CR Femoral Component - Beaded - #1, Left |
| 5513-F-102 | CR Femoral Component - Beaded - #1, Right |
| 5513-F-201 | CR Femoral Component - Beaded - #2, Left |
| 5513-F-202 | CR Femoral Component - Beaded - #2, Right |
| 5513-F-301 | CR Femoral Component - Beaded - #3, Left |
| 5513-F-302 | CR Femoral Component - Beaded - #3, Right |
| 5513-F-401 | CR Femoral Component - Beaded - #4, Left |
| 5513-F-402 | CR Femoral Component - Beaded - #4, Right |
| 5513-F-501 | CR Femoral Component - Beaded - #5, Left |
| 5513-F-502 | CR Femoral Component - Beaded - #5, Right |
| 5513-F-601 | CR Femoral Component - Beaded - #6, Left |
| 5513-F-602 | CR Femoral Component - Beaded - #6, Right |
| 5513-F-701 | CR Femoral Component - Beaded - #7, Left |
| 5513-F-702 | CR Femoral Component - Beaded - #7, Right |
| 5513-F-801 | CR Femoral Component - Beaded - #8, Left |
| 5513-F-802 | CR Femoral Component - Beaded - #8, Right |

**CR Femoral Cementless Component - Beaded with Peri-Apatite Part Numbers**

| | |
|---|---|
| 5517-F-101 | CR Femoral Component - Beaded w/PA - #1, Left |
| 5517-F-102 | CR Femoral Component - Beaded w/PA - #1, Right |
| 5517-F-201 | CR Femoral Component - Beaded w/PA - #2, Left |
| 5517-F-202 | CR Femoral Component - Beaded w/PA - #2, Right |
| 5517-F-301 | CR Femoral Component - Beaded w/PA - #3, Left |
| 5517-F-302 | CR Femoral Component - Beaded w/PA - #3, Right |
| 5517-F-401 | CR Femoral Component - Beaded w/PA - #4, Left |
| 5517-F-402 | CR Femoral Component - Beaded w/PA - #4, Right |
| 5517-F-501 | CR Femoral Component - Beaded w/PA - #5, Left |
| 5517-F-502 | CR Femoral Component - Beaded w/PA - #5, Right |
| 5517-F-601 | CR Femoral Component - Beaded w/PA - #6, Left |
| 5517-F-602 | CR Femoral Component - Beaded w/PA - #6, Right |
| 5517-F-701 | CR Femoral Component - Beaded w/PA - #7, Left |
| 5517-F-702 | CR Femoral Component - Beaded w/PA - #7, Right |
| 5517-F-801 | CR Femoral Component - Beaded w/PA - #8, Left |
| 5517-F-802 | CR Femoral Component - Beaded w/PA - #8, Right |

- **Triathlon PS**

**PS Femoral Cementless Component - Beaded Part Numbers**

| | |
|---|---|
| 5514-F-101 | PS Femoral Component - Beaded - #1, Left |
| 5514-F-102 | PS Femoral Component - Beaded - #1, Right |
| 5514-F-201 | PS Femoral Component - Beaded - #2, Left |
| 5514-F-202 | PS Femoral Component - Beaded - #2, Right |
| 5514-F-301 | PS Femoral Component - Beaded - #3, Left |
| 5514-F-302 | PS Femoral Component - Beaded - #3, Right |
| 5514-F-401 | PS Femoral Component - Beaded - #4, Left |
| 5514-F-402 | PS Femoral Component - Beaded - #4, Right |
| 5514-F-501 | PS Femoral Component - Beaded - #5, Left |
| 5514-F-502 | PS Femoral Component - Beaded - #5, Right |
| 5514-F-601 | PS Femoral Component - Beaded - #6, Left |
| 5514-F-602 | PS Femoral Component - Beaded - #6, Right |
| 5514-F-701 | PS Femoral Component - Beaded - #7, Left |
| 5514-F-702 | PS Femoral Component - Beaded - #7, Right |
| 5514-F-801 | PS Femoral Component - Beaded - #8, Left |
| 5514-F-802 | PS Femoral Component - Beaded - #8, Right |

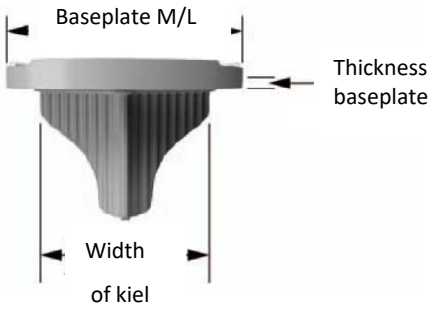
**PS Femoral Cementless Component - Beaded with Peri-Apatite Part Numbers**

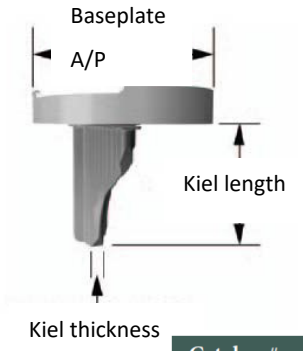
| | |
|---|---|
| 5516-F-101 | PS Femoral Component - Beaded w/PA - #1, Left |
| 5516-F-102 | PS Femoral Component - Beaded w/PA - #1, Right |
| 5516-F-201 | PS Femoral Component - Beaded w/PA - #2, Left |
| 5516-F-202 | PS Femoral Component - Beaded w/PA - #2, Right |
| 5516-F-301 | PS Femoral Component - Beaded w/PA - #3, Left |
| 5516-F-302 | PS Femoral Component - Beaded w/PA - #3, Right |
| 5516-F-401 | PS Femoral Component - Beaded w/PA - #4, Left |
| 5516-F-402 | PS Femoral Component - Beaded w/PA - #4, Right |
| 5516-F-501 | PS Femoral Component - Beaded w/PA - #5, Left |
| 5516-F-502 | PS Femoral Component - Beaded w/PA - #5, Right |
| 5516-F-601 | PS Femoral Component - Beaded w/PA - #6, Left |
| 5516-F-602 | PS Femoral Component - Beaded w/PA - #6, Right |
| 5516-F-701 | PS Femoral Component - Beaded w/PA - #7, Left |
| 5516-F-702 | PS Femoral Component - Beaded w/PA - #7, Right |
| 5516-F-801 | PS Femoral Component - Beaded w/PA - #8, Left |
| 5516-F-802 | PS Femoral Component - Beaded w/PA - #8, Right |

## 2.2. Tibia Component

### 2.2.1. Cemented

- **Triathlon Primary Tibial Baseplate / Universal Tibial Baseplate**




**Primary Tibial Baseplate - Cemented Part Numbers**

| | |
|---|---|
| 5520-B-100 | Primary Tibial Baseplate – Cemented #1 |
| 5520-B-200 | Primary Tibial Baseplate – Cemented #2 |
| 5520-B-300 | Primary Tibial Baseplate – Cemented #3 |
| 5520-B-400 | Primary Tibial Baseplate – Cemented #4 |
| 5520-B-500 | Primary Tibial Baseplate – Cemented #5 |
| 5520-B-600 | Primary Tibial Baseplate – Cemented #6 |
| 5520-B-700 | Primary Tibial Baseplate – Cemented #7 |
| 5520-B-800 | Primary Tibial Baseplate – Cemented #8 |

| Catalog # | Description | |
|---|---|---|
| **Universal Baseplate Tibial Part Numbers** | | |
| 5521-B-100 | Universal Tibial Baseplate | Cemented #1 |
| 5521-B-200 | Universal Tibial Baseplate | Cemented #2 |
| 5521-B-300 | Universal Tibial Baseplate | Cemented #3 |
| 5521-B-400 | Universal Tibial Baseplate | Cemented #4 |
| 5521-B-500 | Universal Tibial Baseplate | Cemented #5 |
| 5521-B-600 | Universal Tibial Baseplate | Cemented #6 |
| 5521-B-700 | Universal Tibial Baseplate | Cemented #7 |
| 5521-B-800 | Universal Tibial Baseplate | Cemented #8 |

## 2.2.2. Cementless

- **Triathlon Primary Tibial Baseplate**

**Primary Tibial Baseplate - Beaded Part Numbers**

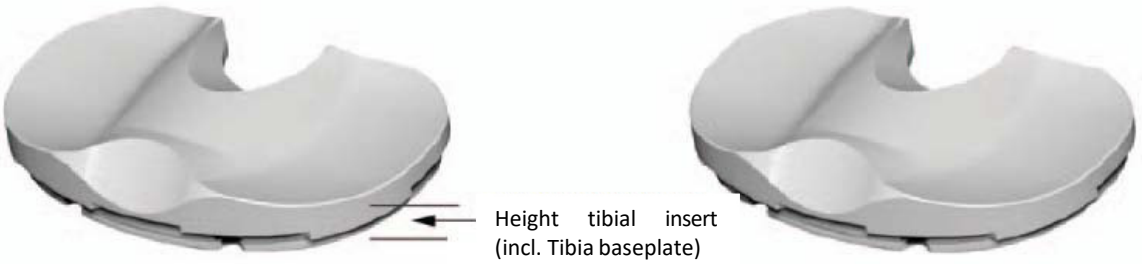
| | |
|---|---|
| 5523-B-100 | Primary Tibial Baseplate - Beaded - #1 |
| 5523-B-200 | Primary Tibial Baseplate - Beaded - #2 |
| 5523-B-300 | Primary Tibial Baseplate - Beaded - #3 |
| 5523-B-400 | Primary Tibial Baseplate - Beaded - #4 |
| 5523-B-500 | Primary Tibial Baseplate - Beaded - #5 |
| 5523-B-600 | Primary Tibial Baseplate - Beaded - #6 |
| 5523-B-700 | Primary Tibial Baseplate - Beaded - #7 |
| 5523-B-800 | Primary Tibial Baseplate - Beaded - #8 |

**Primary Tibial Baseplate - Beaded with Peri-Apatite Part Numbers**

| | |
|---|---|
| 5526-B-100 | Primary Tibial Baseplate - Beaded w/PA - #1 |
| 5526-B-200 | Primary Tibial Baseplate - Beaded w/PA - #2 |
| 5526-B-300 | Primary Tibial Baseplate - Beaded w/PA - #3 |
| 5526-B-400 | Primary Tibial Baseplate - Beaded w/PA - #4 |
| 5526-B-500 | Primary Tibial Baseplate - Beaded w/PA - #5 |
| 5526-B-600 | Primary Tibial Baseplate - Beaded w/PA - #6 |
| 5526-B-700 | Primary Tibial Baseplate - Beaded w/PA - #7 |
| 5526-B-800 | Primary Tibial Baseplate - Beaded w/PA - #8 |

## 2.3. Insert

- **CR Tibial Insert – X3**




**CR Tibial Insert - X3 Part Numbers**

| | |
|---|---|
| 5530-G-109 | CR Tibial Insert - X3 # 1 - 9mm |
| 5530-G-111 | CR Tibial Insert - X3 # 1 - 11mm |
| 5530-G-113 | CR Tibial Insert - X3 # 1 - 13mm |
| 5530-G-116 | CR Tibial Insert - X3 # 1 - 16mm |
| 5530-G-119 | CR Tibial Insert - X3 # 1 - 19mm |

| | |
|---|---|
| 5530-G-209 | CR Tibial Insert - X3 # 2 - 9mm |
| 5530-G-211 | CR Tibial Insert - X3 # 2 - 11mm |
| 5530-G-213 | CR Tibial Insert - X3 # 2 - 13mm |
| 5530-G-216 | CR Tibial Insert - X3 # 2 - 16mm |
| 5530-G-219 | CR Tibial Insert - X3 # 2 - 19mm |

| | |
|---|---|
| 5530-G-309 | CR Tibial Insert - X3 # 3 - 9mm |
| 5530-G-311 | CR Tibial Insert - X3 # 3 - 11mm |
| 5530-G-313 | CR Tibial Insert - X3 # 3 - 13mm |
| 5530-G-316 | CR Tibial Insert - X3 # 3 - 16mm |
| 5530-G-319 | CR Tibial Insert - X3 # 3 - 19mm |

| | |
|---|---|
| 5530-G-409 | CR Tibial Insert - X3 # 4 - 9mm |
| 5530-G-411 | CR Tibial Insert - X3 # 4 - 11mm |
| 5530-G-413 | CR Tibial Insert - X3 # 4 - 13mm |
| 5530-G-416 | CR Tibial Insert - X3 # 4 - 16mm |
| 5530-G-419 | CR Tibial Insert - X3 # 4 - 19mm |

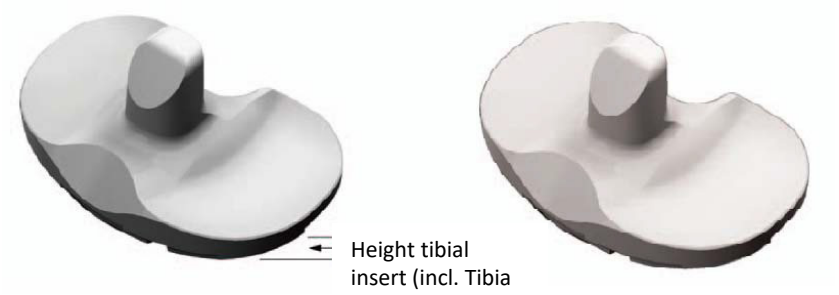
| | |
|---|---|
| 5530-G-509 | CR Tibial Insert - X3 # 5 - 9mm |
| 5530-G-511 | CR Tibial Insert - X3 # 5 - 11mm |
| 5530-G-513 | CR Tibial Insert - X3 # 5 - 13mm |
| 5530-G-516 | CR Tibial Insert - X3 # 5 - 16mm |
| 5530-G-519 | CR Tibial Insert - X3 # 5 - 19mm |

| | |
|---|---|
| 5530-G-609 | CR Tibial Insert - X3 # 6 - 9mm |
| 5530-G-611 | CR Tibial Insert - X3 # 6 - 11mm |
| 5530-G-613 | CR Tibial Insert - X3 # 6 - 13mm |
| 5530-G-616 | CR Tibial Insert - X3 # 6 - 16mm |
| 5530-G-619 | CR Tibial Insert - X3 # 6 - 19mm |

| | |
|---|---|
| 5530-G-709 | CR Tibial Insert - X3 # 7 - 9mm |
| 5530-G-711 | CR Tibial Insert - X3 # 7 - 11mm |
| 5530-G-713 | CR Tibial Insert - X3 # 7 - 13mm |
| 5530-G-716 | CR Tibial Insert - X3 # 7 - 16mm |
| 5530-G-719 | CR Tibial Insert - X3 # 7 - 19mm |

| | |
|---|---|
| 5530-G-809 | CR Tibial Insert - X3 # 8 - 9mm |
| 5530-G-811 | CR Tibial Insert - X3 # 8 - 11mm |
| 5530-G-813 | CR Tibial Insert - X3 # 8 - 13mm |
| 5530-G-816 | CR Tibial Insert - X3 # 8 - 16mm |
| 5530-G-819 | CR Tibial Insert - X3 # 8 - 19mm |

- **PS Tibial Insert – X3**



Height tibial insert (incl. Tibia baseplate)

**PS Tibial Insert - X3 Part Numbers**

| | |
|---|---|
| 5532-G-109 | PS Tibial Insert - X3 # 1 - 9mm |
| 5532-G-111 | PS Tibial Insert - X3 # 1 - 11mm |
| 5532-G-113 | PS Tibial Insert - X3 # 1 - 13mm |
| 5532-G-116 | PS Tibial Insert - X3 # 1 - 16mm |
| 5532-G-119 | PS Tibial Insert - X3 # 1 - 19mm |
| 5532-G-122 | PS Tibial Insert - X3 # 1 - 22mm |
| 5532-G-125 | PS Tibial Insert - X3 # 1 - 25mm |
| 5532-G-209 | PS Tibial Insert - X3 # 2 - 9mm |
| 5532-G-211 | PS Tibial Insert - X3 # 2 - 11mm |
| 5532-G-213 | PS Tibial Insert - X3 # 2 - 13mm |
| 5532-G-216 | PS Tibial Insert - X3 # 2 - 16mm |
| 5532-G-219 | PS Tibial Insert - X3 # 2 - 19mm |
| 5532-G-222 | PS Tibial Insert - X3 # 2 - 22mm |
| 5532-G-225 | PS Tibial Insert - X3 # 2 - 25mm |
| 5532-G-309 | PS Tibial Insert - X3 # 3 - 9mm |
| 5532-G-311 | PS Tibial Insert - X3 # 3 - 11mm |
| 5532-G-313 | PS Tibial Insert - X3 # 3 - 13mm |
| 5532-G-316 | PS Tibial Insert - X3 # 3 - 16mm |
| 5532-G-319 | PS Tibial Insert - X3 # 3 - 19mm |
| 5532-G-322 | PS Tibial Insert - X3 # 3 - 22mm |
| 5532-G-325 | PS Tibial Insert - X3 # 3 - 25mm |

**PS Tibial Insert - X3 Part Numbers - Continued**

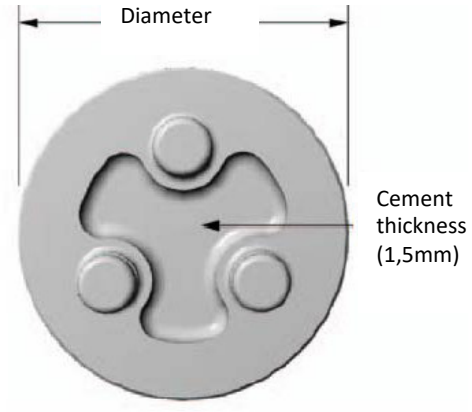
| | |
|---|---|
| 5532-G-409 | PS Tibial Insert - X3 # 4 - 9mm |
| 5532-G-411 | PS Tibial Insert - X3 # 4 - 11mm |
| 5532-G-413 | PS Tibial Insert - X3 # 4 - 13mm |
| 5532-G-416 | PS Tibial Insert - X3 # 4 - 16mm |
| 5532-G-419 | PS Tibial Insert - X3 # 4 - 19mm |
| 5532-G-422 | PS Tibial Insert - X3 # 4 - 22mm |
| 5532-G-425 | PS Tibial Insert - X3 # 4 - 25mm |
| 5532-G-509 | PS Tibial Insert - X3 # 5 - 9mm |
| 5532-G-511 | PS Tibial Insert - X3 # 5 - 11mm |
| 5532-G-513 | PS Tibial Insert - X3 # 5 - 13mm |
| 5532-G-516 | PS Tibial Insert - X3 # 5 - 16mm |
| 5532-G-519 | PS Tibial Insert - X3 # 5 - 19mm |
| 5532-G-522 | PS Tibial Insert - X3 # 5 - 22mm |
| 5532-G-525 | PS Tibial Insert - X3 # 5 - 25mm |
| 5532-G-609 | PS Tibial Insert - X3 # 6 - 9mm |
| 5532-G-611 | PS Tibial Insert - X3 # 6 - 11mm |
| 5532-G-613 | PS Tibial Insert - X3 # 6 - 13mm |
| 5532-G-616 | PS Tibial Insert - X3 # 6 - 16mm |
| 5532-G-619 | PS Tibial Insert - X3 # 6 - 19mm |
| 5532-G-622 | PS Tibial Insert - X3 # 6 - 22mm |
| 5532-G-625 | PS Tibial Insert - X3 # 6 - 25mm |
| 5532-G-709 | PS Tibial Insert - X3 # 7 - 9mm |
| 5532-G-711 | PS Tibial Insert - X3 # 7 - 11mm |
| 5532-G-713 | PS Tibial Insert - X3 # 7 - 13mm |
| 5532-G-716 | PS Tibial Insert - X3 # 7 - 16mm |
| 5532-G-719 | PS Tibial Insert - X3 # 7 - 19mm |
| 5532-G-722 | PS Tibial Insert - X3 # 7 - 22mm |
| 5532-G-725 | PS Tibial Insert - X3 # 7 - 25mm |
| 5532-G-809 | PS Tibial Insert - X3 # 8 - 9mm |
| 5532-G-811 | PS Tibial Insert - X3 # 8 - 11mm |
| 5532-G-813 | PS Tibial Insert - X3 # 8 - 13mm |
| 5532-G-816 | PS Tibial Insert - X3 # 8 - 16mm |
| 5532-G-819 | PS Tibial Insert - X3 # 8 - 19mm |
| 5532-G-822 | PS Tibial Insert - X3 # 8 - 22mm |
| 5532-G-825 | PS Tibial Insert - X3 # 8 - 25mm |

- **CS Tibial insert – X3**

| Size | Part Number | Thickness | Description |
|---|---|---|---|
| 1 | 5531-G-109 | 9mm | Triathlon CS Lipped Insert |
| 1 | 5531-G-111 | 11mm | Triathlon CS Lipped Insert |
| 1 | 5531-G-113 | 13mm | Triathlon CS Lipped Insert |
| 1 | 5531-G-116 | 16mm | Triathlon CS Lipped Insert |
| 1 | 5531-G-119 | 19mm | Triathlon CS Lipped Insert |
| 1 | 5531-G-122 | 22mm | Triathlon CS Lipped Insert |
| 1 | 5531-G-125 | 25mm | Triathlon CS Lipped Insert |
| 2 | 5531-G-209 | 9mm | Triathlon CS Lipped Insert |
| 2 | 5531-G-211 | 11mm | Triathlon CS Lipped Insert |
| 2 | 5531-G-213 | 13mm | Triathlon CS Lipped Insert |
| 2 | 5531-G-216 | 16mm | Triathlon CS Lipped Insert |
| 2 | 5531-G-219 | 19mm | Triathlon CS Lipped Insert |
| 2 | 5531-G-222 | 22mm | Triathlon CS Lipped Insert |
| 2 | 5531-G-225 | 25mm | Triathlon CS Lipped Insert |
| 3 | 5531-G-309 | 9mm | Triathlon CS Lipped Insert |
| 3 | 5531-G-311 | 11mm | Triathlon CS Lipped Insert |
| 3 | 5531-G-313 | 13mm | Triathlon CS Lipped Insert |
| 3 | 5531-G-316 | 16mm | Triathlon CS Lipped Insert |
| 3 | 5531-G-319 | 19mm | Triathlon CS Lipped Insert |
| 3 | 5531-G-322 | 22mm | Triathlon CS Lipped Insert |
| 3 | 5531-G-325 | 25mm | Triathlon CS Lipped Insert |
| 4 | 5531-G-409 | 9mm | Triathlon CS Lipped Insert |
| 4 | 5531-G-411 | 11mm | Triathlon CS Lipped Insert |
| 4 | 5531-G-413 | 13mm | Triathlon CS Lipped Insert |
| 4 | 5531-G-416 | 16mm | Triathlon CS Lipped Insert |
| 4 | 5531-G-419 | 19mm | Triathlon CS Lipped Insert |
| 4 | 5531-G-422 | 22mm | Triathlon CS Lipped Insert |
| 4 | 5531-G-425 | 25mm | Triathlon CS Lipped Insert |
| 5 | 5531-G-509 | 9mm | Triathlon CS Lipped Insert |
| 5 | 5531-G-511 | 11mm | Triathlon CS Lipped Insert |
| 5 | 5531-G-513 | 13mm | Triathlon CS Lipped Insert |
| 5 | 5531-G-516 | 16mm | Triathlon CS Lipped Insert |
| 5 | 5531-G-519 | 19mm | Triathlon CS Lipped Insert |
| 5 | 5531-G-522 | 22mm | Triathlon CS Lipped Insert |
| 5 | 5531-G-525 | 25mm | Triathlon CS Lipped Insert |
| 6 | 5531-G-609 | 9mm | Triathlon CS Lipped Insert |
| 6 | 5531-G-611 | 11mm | Triathlon CS Lipped Insert |
| 6 | 5531-G-613 | 13mm | Triathlon CS Lipped Insert |
| 6 | 5531-G-616 | 16mm | Triathlon CS Lipped Insert |
| 6 | 5531-G-619 | 19mm | Triathlon CS Lipped Insert |
| 6 | 5531-G-622 | 22mm | Triathlon CS Lipped Insert |
| 6 | 5531-G-625 | 25mm | Triathlon CS Lipped Insert |
| 7 | 5531-G-709 | 9mm | Triathlon CS Lipped Insert |
| 7 | 5531-G-711 | 11mm | Triathlon CS Lipped Insert |
| 7 | 5531-G-713 | 13mm | Triathlon CS Lipped Insert |
| 7 | 5531-G-716 | 16mm | Triathlon CS Lipped Insert |
| 7 | 5531-G-719 | 19mm | Triathlon CS Lipped Insert |
| 7 | 5531-G-722 | 22mm | Triathlon CS Lipped Insert |
| 7 | 5531-G-725 | 25mm | Triathlon CS Lipped Insert |
| 8 | 5531-G-809 | 9mm | Triathlon CS Lipped Insert |
| 8 | 5531-G-811 | 11mm | Triathlon CS Lipped Insert |
| 8 | 5531-G-813 | 13mm | Triathlon CS Lipped Insert |
| 8 | 5531-G-816 | 16mm | Triathlon CS Lipped Insert |
| 8 | 5531-G-819 | 19mm | Triathlon CS Lipped Insert |
| 8 | 5531-G-822 | 22mm | Triathlon CS Lipped Insert |
| 8 | 5531-G-825 | 25mm | Triathlon CS Lipped Insert |

## 2.4. Patella (optional), cemented

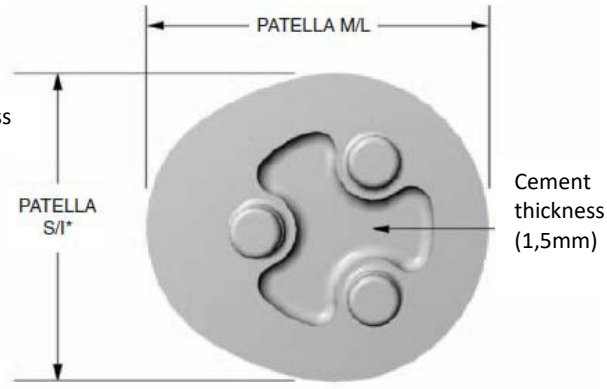
- **Symmetric – X3**


**Symmetric Patella - X3 Part Numbers**

| | |
|---|---|
| 5550-G-278 | Symmetric Patella - X3 - S27mm x 8mm |
| 5550-G-298 | Symmetric Patella - X3 - S29mm x 8mm |
| 5550-G-319 | Symmetric Patella - X3 - S31mm x 9mm |
| 5550-G-339 | Symmetric Patella - X3 - S33mm x 9mm |
| 5550-G-360 | Symmetric Patella - X3 - S36mm x 10mm |
| 5550-G-391 | Symmetric Patella - X3 - S39mm x 11mm |

- **Asymmetric – X3**


**Asymmetric Patella - X3 Part Numbers**

| | |
|---|---|
| 5551-G-299 | Asymmetric Patella - X3 - A29mm (S/I*) x 9mm |
| 5551-G-320 | Asymmetric Patella - X3 - A32mm (S/I*) x 10mm |
| 5551-G-350 | Asymmetric Patella - X3 - A35mm (S/I*) x 10mm |
| 5551-G-381 | Asymmetric Patella - X3 - A38mm (S/I*) x 11mm |
| 5551-G-401 | Asymmetric Patella - X3 - A40mm (S/I*) x 11mm |

## 3. Triathlon PKR


**Femoral Component**

**X3 Insert**

**Tibial Baseplate**

### 3.1. Femoral Components, cemented

| Catalog # | Description |
|---|---|
| Triathlon PKR Femur Part Numbers | |
| 5610-F-101 | Triathlon PKR Femur #1 LM/RL |
| 5610-F-201 | Triathlon PKR Femur #2 LM/RL |
| 5610-F-301 | Triathlon PKR Femur #3 LM/RL |
| 5610-F-401 | Triathlon PKR Femur #4 LM/RL |
| 5610-F-501 | Triathlon PKR Femur #5 LM/RL |
| 5610-F-601 | Triathlon PKR Femur #6 LM/RL |
| 5610-F-102 | Triathlon PKR Femur #1 RM/LL |
| 5610-F-202 | Triathlon PKR Femur #2 RM/LL |
| 5610-F-302 | Triathlon PKR Femur #3 RM/LL |
| 5610-F-402 | Triathlon PKR Femur #4 RM/LL |
| 5610-F-502 | Triathlon PKR Femur #5 RM/LL |
| 5610-F-602 | Triathlon PKR Femur #6 RM/LL |

## 3.2. Tibia Baseplate, cemented

### Triathlon PKR Baseplate Part Numbers

| | |
|---|---|
| **5620-B-101** | Triathlon PKR Baseplate #1 LM/RL |
| **5620-B-201** | Triathlon PKR Baseplate #2 LM/RL |
| **5620-B-301** | Triathlon PKR Baseplate #3 LM/RL |
| **5620-B-401** | Triathlon PKR Baseplate #4 LM/RL |
| **5620-B-501** | Triathlon PKR Baseplate #5 LM/RL |
| **5620-B-601** | Triathlon PKR Baseplate #6 LM/RL |
| **5620-B-102** | Triathlon PKR Baseplate #1 RM/LL |
| **5620-B-202** | Triathlon PKR Baseplate #2 RM/LL |
| **5620-B-302** | Triathlon PKR Baseplate #3 RM/LL |
| **5620-B-402** | Triathlon PKR Baseplate #4 RM/LL |
| **5620-B-502** | Triathlon PKR Baseplate #5 RM/LL |
| **5620-B-602** | Triathlon PKR Baseplate #6 RM/LL |

## 3.3. Insert

| Catalog # | Description |
|---|---|
| Triathlon PKR Insert Part Numbers | |
| 5630-G-108 | Triathlon PKR Insert X3 #1 LM/RL - 8mm |
| 5630-G-109 | Triathlon PKR Insert X3 #1 LM/RL - 9mm |
| 5630-G-110 | Triathlon PKR Insert X3 #1 LM/RL - 10mm |
| 5630-G-112 | Triathlon PKR Insert X3 #1 LM/RL - 12mm |
| 5630-G-128 | Triathlon PKR Insert X3 #1 RM/LL - 8mm |
| 5630-G-129 | Triathlon PKR Insert X3 #1 RM/LL - 9mm |
| 5630-G-120 | Triathlon PKR Insert X3 #1 RM/LL - 10mm |
| 5630-G-122 | Triathlon PKR Insert X3 #1 RM/LL - 12mm |
| 5630-G-208 | Triathlon PKR Insert X3 #2 LM/RL - 8mm |
| 5630-G-209 | Triathlon PKR Insert X3 #2 LM/RL - 9mm |
| 5630-G-210 | Triathlon PKR Insert X3 #2 LM/RL - 10mm |
| 5630-G-212 | Triathlon PKR Insert X3 #2 LM/RL - 12mm |
| 5630-G-228 | Triathlon PKR Insert X3 #2 RM/LL -8mm |
| 5630-G-229 | Triathlon PKR Insert X3 #2 RM/LL - 9mm |
| 5630-G-220 | Triathlon PKR Insert X3 #2 RM/LL - 10mm |
| 5630-G-222 | Triathlon PKR Insert X3 #2 RM/LL - 12mm |
| 5630-G-308 | Triathlon PKR Insert X3 #3 LM/RL - 8mm |
| 5630-G-309 | Triathlon PKR Insert X3 #3 LM/RL - 9mm |
| 5630-G-310 | Triathlon PKR Insert X3 #3 LM/RL - 10mm |
| 5630-G-312 | Triathlon PKR Insert X3 #3 LM/RL -12mm |
| 5630-G-328 | Triathlon PKR Insert X3 #3 RM/LL - 8mm |
| 5630-G-329 | Triathlon PKR Insert X3 #3 RM/LL - 9mm |
| 5630-G-320 | Triathlon PKR Insert X3 #3 RM/LL - 10mm |
| 5630-G-322 | Triathlon PKR Insert X3 #3 RM/LL - 12mm |

| Catalog # | Description |
|---|---|
| Triathlon PKR Insert Part Numbers | |
| 5630-G-408 | Triathlon PKR Insert X3 #4 LM/RL -8mm |
| 5630-G-409 | Triathlon PKR Insert X3 #4 LM/RL -9mm |
| 5630-G-410 | Triathlon PKR Insert X3 #4 LM/RL -10mm |
| 5630-G-412 | Triathlon PKR Insert X3 #4 LM/RL -12mm |
| 5630-G-428 | Triathlon PKR Insert X3 #4 RM/LL -8mm |
| 5630-G-429 | Triathlon PKR Insert X3 #4 RM/LL -9mm |
| 5630-G-420 | Triathlon PKR Insert X3 #4 RM/LL -10mm |
| 5630-G-422 | Triathlon PKR Insert X3 #4 RM/LL -12mm |
| 5630-G-508 | Triathlon PKR Insert X3 #5 LM/RL -8mm |
| 5630-G-509 | Triathlon PKR Insert X3 #5 LM/RL -9mm |
| 5630-G-510 | Triathlon PKR Insert X3 #5 LM/RL -10mm |
| 5630-G-512 | Triathlon PKR Insert X3 #5 LM/RL -12mm |
| 5630-G-528 | Triathlon PKR Insert X3 #5 RM/LL -8mm |
| 5630-G-529 | Triathlon PKR Insert X3 #5 RM/LL -9mm |
| 5630-G-520 | Triathlon PKR Insert X3 #5 RM/LL -10mm |
| 5630-G-522 | Triathlon PKR Insert X3 #5 RM/LL -12mm |
| 5630-G-608 | Triathlon PKR Insert X3 #6 LM/RL -8mm |
| 5630-G-609 | Triathlon PKR Insert X3 #6 LM/RL -9mm |
| 5630-G-610 | Triathlon PKR Insert X3 #6 LM/RL -10mm |
| 5630-G-612 | Triathlon PKR Insert X3 #6 LM/RL -12mm |
| 5630-G-628 | Triathlon PKR Insert X3 #6 RM/LL -8mm |
| 5630-G-629 | Triathlon PKR Insert X3 #6 RM/LL -9mm |
| 5630-G-620 | Triathlon PKR Insert X3 #6 RM/LL -10mm |
| 5630-G-622 | Triathlon PKR Insert X3 #6 RM/LL -12mm |