Summary of safety and clinical performance

(SSCP)

Intended for Patients

[U2 Total Knee System]

[English]

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Rev. 2

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This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients of lay persons. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instructions For Use to provide information on the safe use of the device.

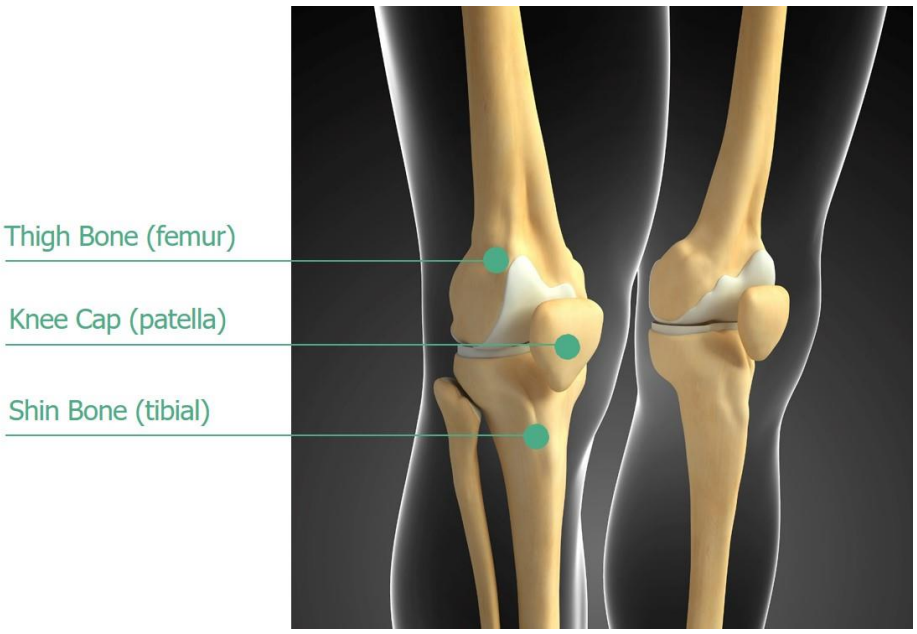
1. Device identification and general information

Device Trade Name	U2 Total Knee System
Basic UDI-DI	471987216TD-III-004-1SE, 471987216TD-III-004-2SG, 471987216TD-III-004-3SJ, 471987216TD-III-004-4SL, 471987216TD-III-004-5SN, 471987216TD-III-004-6SQ, 471987216TD-III-004-7SS, 471987216TD-III-004-8SU, 471987216TD-III-004-9SW, 471987216TD-III-004-10GU, 471987216TD-III-004-11GW, 471987216TD-III-004-12GY, 471987216TD-III-004-13H2
Manufacturer	United Orthopedic Corporation
Address	No 16, Luke 1st Rd., Luzhu Dist., Kaohsiung City, 82151 Taiwan.
First Year of CE Certificate	2005

2. Intended use of the device

2.1. What is the device used for? (Intended purpose)

The purpose of this document is to help you know more about the U2 Total Knee System. If your knee joint is damaged due to certain kinds of arthritis, the cartilage and bone of the knee joint become worn out. It may get harder to move and become painful over time. Then the total knee replacement surgery is one of the treatment methods. The total knee replacement surgery is intended to provide increased patient mobility and reduce pain. In this surgery, the doctor removes the damaged areas and replaced with artificial implants. If you want to know more about your knee joint, please check the picture as shown as below. The knee consists of thigh bone (femur), shin bone (tibia) and knee cap (patella).



The U2 Total Knee System intended for patients who require total knee replacement surgery. This device is single use only and provide sterile.

2.2. For what conditions do doctor use the device? (Indications and intended patient groups)

The U2 Total Knee System can be used in skeletally mature patients with severe knee pain and disability due to:

- Rheumatoid arthritis/ Collagen disorders: An autoimmune and inflammatory disease attack the joints.
- Osteoarthritis/Polyarthritis: Non inflammatory disease. A loss of bone and/or cartilage in the knee joint that may lead to pain and stiffness.
- Traumatic Arthritis: A condition that results in loss of bone and/or cartilage in the knee joint after a knee injury.
- Avascular Necrosis: A condition that results in death of the bone.

The U2 Total knee System - Tibial baseplate, TPS+ can be used in skeletally mature patients with severe knee pain and disability due to:

- Osteoarthritis/Polyarthritis: Non inflammatory disease. A loss of bone and/or cartilage in the knee joint that may lead to pain and stiffness.

2.3. Who should not have the device? (Contraindications)

Your doctor may decide that total knee replacement surgery is not suitable for you if:

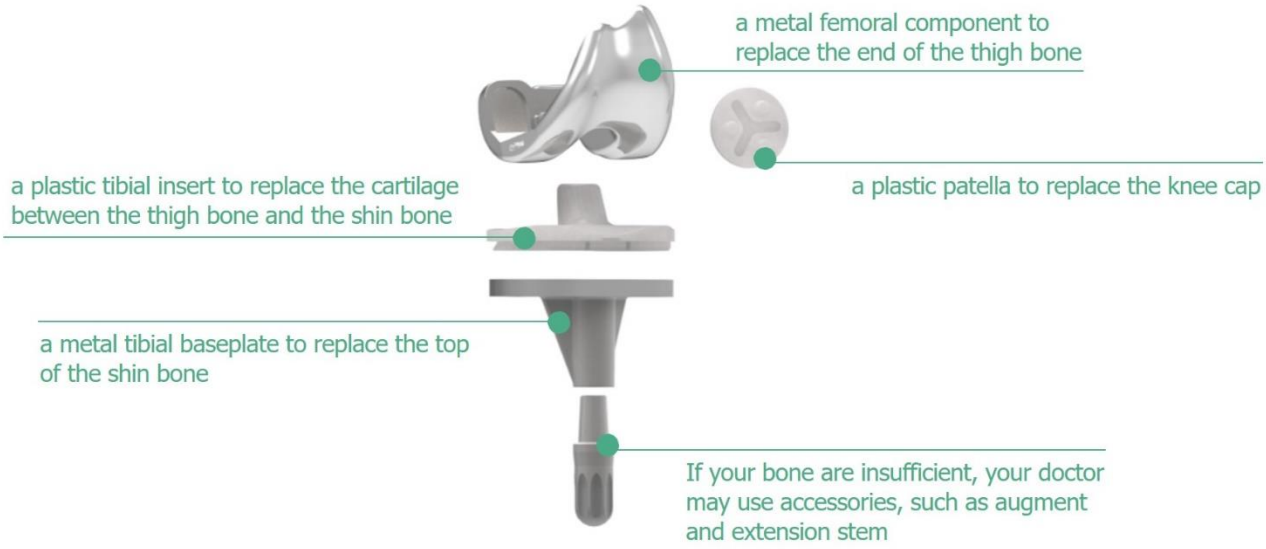
- You currently have knee joint infections.
- Your bone is not strong enough.
- Your joint tissue is not stable.
- Your skeletal is not mature.
- You are fever or leukocytosis.

3. Device description

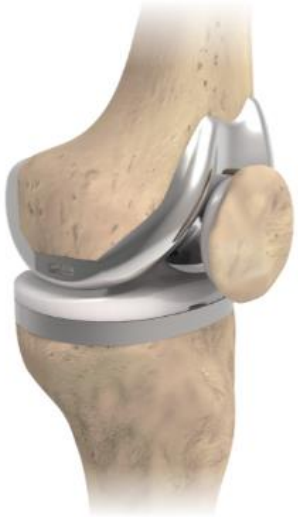
3.1. What is the U2 Total Knee System? (Device description)

The U2 Total Knee System is used for total knee replacement. It provides a full range of interchangeable design options with multiple tibial insert choices.

An overview is described in picture below.



If you received the total knee replacement surgery, the expected consequence will be the picture shown below.



3.2. Do the device contain medicinal? (Information about medicinal substances in the device)

None. None of medicinal substances contain in the U2 Total Knee System.

3.3. Description of how the device is achieving its intended mode of action

The U2 Total Knee System is intended to achieve what your knee work. It is implanted to the knee where the thigh bone and the shin bone meet. The other bones include the fibula, the smaller bone sitting alongside the tibial, and the knee cap. Tendons in the knee connect the bones to muscles and ligaments which join the knee bones together. Cartilage covers the ends of the thigh bone, shin bone, and kneecap. It cushions the knee and helps it move easily. When all parts of the knee are working

together, the knee operates smoothly to flex and extend the lower leg. If the knee is damaged by disease, wear, or injury, it may not work properly and can cause pain, weakness, or other problems.

3.4. Description of accessories

Accessories will help your surgery proceed smoothly. If your shin bone is insufficient, your doctor may use augment or extension stem. In addition, your doctor will use knee instruments to complete your surgery.

4. Risks and warnings

4.1. How potential risks have been controlled or managed

All the potential risks have been controlled to reduce risk as low as possible by following the risk management standards ISO 14971 “Medical devices – Application of risk management to medical devices”. This standard is the risk management standard specified used in medical device industries.

4.2. What are the risks of having this surgery? (Remaining risks and undesirable effects)

The following risks have been associated with total knee replacement. These include but are not limited to:

- Adverse local tissue reaction
- Dislocation
- Loosening
- Dissociation
- Implant breakage
- Impingement
- Instability
- Wear
- Osteolysis
- Periprosthetic fracture
- Subsidence
- Noise
- Revision
- Leg length discrepancy
- Implant fracture
- Malalignment
- Allergic reaction
- Infection
- Pain
- Stiffness
- Fracture
- Soft tissue complication
- Hematoma
- Thrombosis
- Wound complication
- Neurological complication
- Surgical complication
- Swelling
- Trauma
- Mental health complication
- Size mismatch
- Others

4.3. What are the things you must do to avoid potentially serious harm if implanted with the device? (Warnings and Precautions)

- Before having surgery, tell your doctor to avoid using the U2 Total Knee System with another

manufacturer's total knee replacement components because it may affect the compatibility of the components.

- To keeping your quality of life, do not have a large number of activities such as sports (football, running, muscle strain, etc.) that will place too much stress on the knee joint. Please follow your doctor's recommendations for weight management. Your artificial knee joint may fail and does not work if too much stress is placed on it.
- For those not recommended activities and work after surgery, please follow your doctor's recommendations and physical therapy schedule. Your doctor will give you instructions based on you and your knee implant.
- Inform your doctor if you have signs of infection such as joint pain close to the surgical site, fever, chills, redness, etc.
- Regular X-rays shall be taken. To evaluate if the implant move, loose, bend, fracture or the cement or bone loss. If one of these conditions occur, please pay attention to it and consider the advantage of revision.

4.4. Have any adverse events ever occurred to the device? (Summary of any field safety corrective action and field safety notice)

A field safety corrective action is any action taken to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device. It is required when it becomes necessary for the medical device owner to take action to eliminate, or reduce the risk of the identified hazards. The field safety corrective action may include but not limited:

- The return of the device to the product owner.
- Inspection or examination of the device by user.
- Modification of the device. For example, advice relating to a change in the way the device is used.
- Exchange of device.
- Destruction of device.
- Retrofit by purchaser.
- Advice given by the product owner regarding the use of the device.
- Advice given by the product owner regarding follow up of patients, users, or others.
- Recall of device.

Until now (the date issued of this document), 285,779 sets of the U2 Total Knee System have been sold to the worldwide. There is only one field safety corrective action (recall) related to mislabeled issue in 2017. Considering this issue may cause the doctor confused and surgery delayed, we conducted a recall of the affected device. The affected devices were recall from Pakistan/Taiwan/Iran/South Africa/ USA/ Korea /China /UK /Greece /Italy /Switzerland /France /Ireland and completed in 2018.

Until now (the date issued of this document), 5,371 sets of the U2 Total knee System - Tibial baseplate, TPS+ have been sold to the worldwide. There is no FSCA (recall) repot.

5. Summary of clinical evaluation and post-market clinical follow-up

Clinical performance conclusions

In the clinical study to support the device, the performance of the device was evaluated based upon survival rate and scores and summarized as table below.

U2 Total Knee System			
Items to evaluate		**What we expected**	**Clinical results**
Clinical Performance	Knee Society Score – Knee Score (KSS)	good to excellent (average ≥ 70 points)	excellent (90.1 points)
	Survival rate 10 years	> 94%	98.95%
U2 Total Knee System - Tibial baseplate, TPS+			
Items to evaluate		**What we expected**	**Clinical results**
Clinical Performance	Oxford Knee Score (OKS)	good to excellent (average ≥ 34 points)	excellent (44.0 points)
	Survival rate 10 years	≥ 95.0%	98.8%*

*The PMCF is continued to achieve maximum follow-up of 10 years based on our PMCF plan to confirm its safety and performance.

Clinical safety conclusions

In the clinical study to support the device, the safety of the device was evaluated based upon adverse event.

After surgery (postoperatively), the complications or adverse events were reported and summarized as table below.

U2 Total Knee System		
Complications or adverse events	**Number of knees with complications or adverse event out of the total number of knees in the study**	**Percent (%) of patients who had this adverse event**
Manipulation under anesthesia (MUA)	10 out of 2,076	0.5%
Articular stiffness	4 out of 2,076	0.2%
Patella dislocation	4 out of 2,076	0.2%
Infection	2 out of 2,076	0.1%

Deep vein thrombosis	2 out of 2,076	0.1%
Cerebrovascular accident	2 out of 2,076	0.1%
Periprosthetic fracture	3 out of 2,076	0.1%
Patellar pain and wear	2 out of 2,076	0.1%
Tibial bone split	1 out of 2,076	<0.1%
Pulmonary embolism	1 out of 2,076	<0.1%
Hematoma arthritis	1 out of 2,076	<0.1%
Loosening	1 out of 2,076	<0.1%
Wound healing	1 out of 2,076	<0.1%
Patellar instability	1 out of 2,076	<0.1%
Heterotopic ossification	1 out of 2,076	<0.1%
Ligament/tendon injury	1 out of 2,076	<0.1%
Arthrofibrosis	1 out of 2,076	<0.1%
U2 Total Knee System - Tibial baseplate, TPS+		
Complications or adverse events	**Total number of patients who reported this adverse event out of the total number of knees in the study**	**Percent (%) of patients who had this adverse event**
Pain	1 out of 81	1.2%
Fracture	1 out of 81	1.2%

In conclusion, the study data indicates that, U2 Total Knee System, has achieved the clinical performance, which used in skeletally mature patients requiring total knee arthroplasty.

6. What other treatments? (Possible diagnostic or therapeutic alternatives)

If you are considering alternative treatments, please consult your doctor. Your doctor can make suggestions based on your age, general health, and the condition of your knee. The alternative treatments may include but not limited:

- Nonsurgical treatment:
  - non-pharmacological treatments;
  - pharmacological treatment;
  - cell therapy.
- Other surgical treatment:
  - patellar resurfacing, joint aspiration, joint distraction, joint lavage
  - arthroscopic debridement;
  - cartilage repair technique
  - osteotomy

- different type joint replacement;
- internal fixation.

7. Who are qualified to use the device? (Suggested training for users)

If you are advised to treat with total knee replacement and implant the U2 Total Knee System, your surgery will be performed by certified Orthopedist.

8. More information

This document is provided to give you information about your treatment choices. It is not intended to replace advice from a doctor. If you have any further questions or need additional information about the U2 Total Knee System, please discuss with your doctor.

9. History of revisions

SSCP revision No.	**Date issued (DD-MM-YYYY)**	**Change description**	**Revision validated by the Notified Body**
0	29-05-2025	First issue.	☒Yes Validation language: English ☐No
1	22-12-2025	Annually update.	☒Yes Validation language: English ☐No
2	10-03-2026	1. Update the EMDN code. 2. Add information regarding the extension line product, U2 Total Knee System – Tibial Baseplate, TPS+, which was certified under MDR on 08 January 2026.	☒Yes Validation language: English *This version consolidates the SSCP contents of the U2 Total Knee System and the U2 Total Knee System – Tibial Baseplate, TPS+, both of which were validated during MDR certification. ☐No