Summary of safety and clinical performance
(SSCP)

Intended for Patients

[U2 Total Knee System – PSA Type]

[English]

www.unitedorthopedic.com

UOC-SSCP-EN-00003

Rev. 2

Document revision: 2
Date issued: 26-12-2025

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.

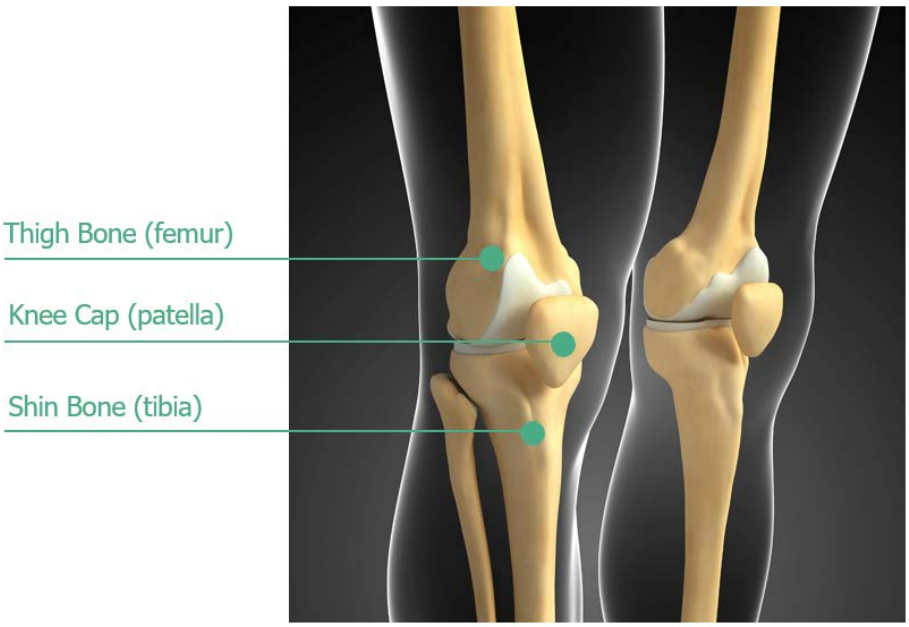
1. Device identification and general information

Device Trade Name	• U2 Total Knee System – PSA Type • Knee Accessories
Basic UDI-DI	• 471987216TD-III-007-1SV Femoral Component, PSA • 471987216TD-III-007-2SX Tibial Insert, PSA • 471987216TD-III-007-3SZ Tibial Baseplate, PSA, Screw Locking • 471987216TD-III-007-4T3 Straight Stem, PSA • 471987216TD-III-007-5T5 Curved Stem, PSA • 471987216TD-III-007-6T7 Offset Stem Adapter, PSA • 471987216TD-III-007-7T9 Femoral Screw, PSA, M5 • 471987216TD-IIb-015-15H U2 Total Knee System Tibial Augment, MBA • 471987216TD-IIb-015-25K U2 Total Knee System Femoral Augment Set, PSA, Posterior • 471987216TD-IIb-015-35M U2 Total Knee System Femoral Augment Set, PSA, Distal • 471987216TD-IIb-015-45P U2 Total Knee System Femoral Augment Set, Distal Only • 471987216TD-IIb-015-55R U2 Total Knee System Tibial Augment Set, Screw Locking • 471987216TD-IIb-015-65T U2 Total Knee System Tibial plug • 471987216TD-IIb-015-75V U2 Total Knee System Tibial screw
Manufacturer	United Orthopedic Corporation
Address	No. 16, Luke 1st Rd. Luzhu Dist., Kaohsiung City 82151, Taiwan.
First Year of CE Certificate	2008

2. Intended purpose and other indications

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 – PSA Type. 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. Revision Total knee replacement surgery is one of the treatment methods. 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).



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

This device is indicated in revision total knee arthroplasty in skeletally mature patients with following conditions:

- Revision procedures when other treatments or devices have failed.

This device is a single use implant and intended for cemented use only.

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

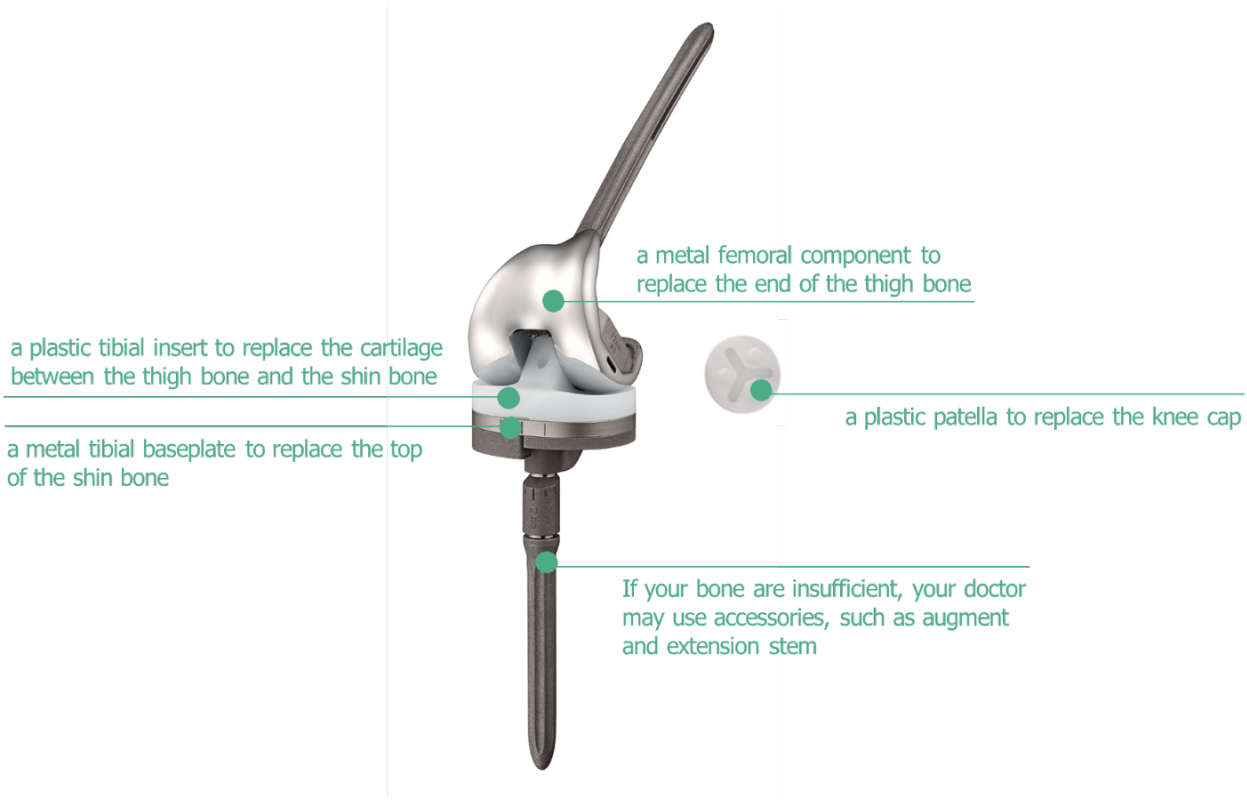
Your doctor may decide that total knee replacement surgery is not suitable for you if:

- You currently have knee joint infections.
- Your skeletal is not mature.
- You have unstable mental state or neuromuscular disorders, which may make you injured in your after surgery care.
- You have a breakdown of the skin, an ulcer of the skin or a history of recurrent.

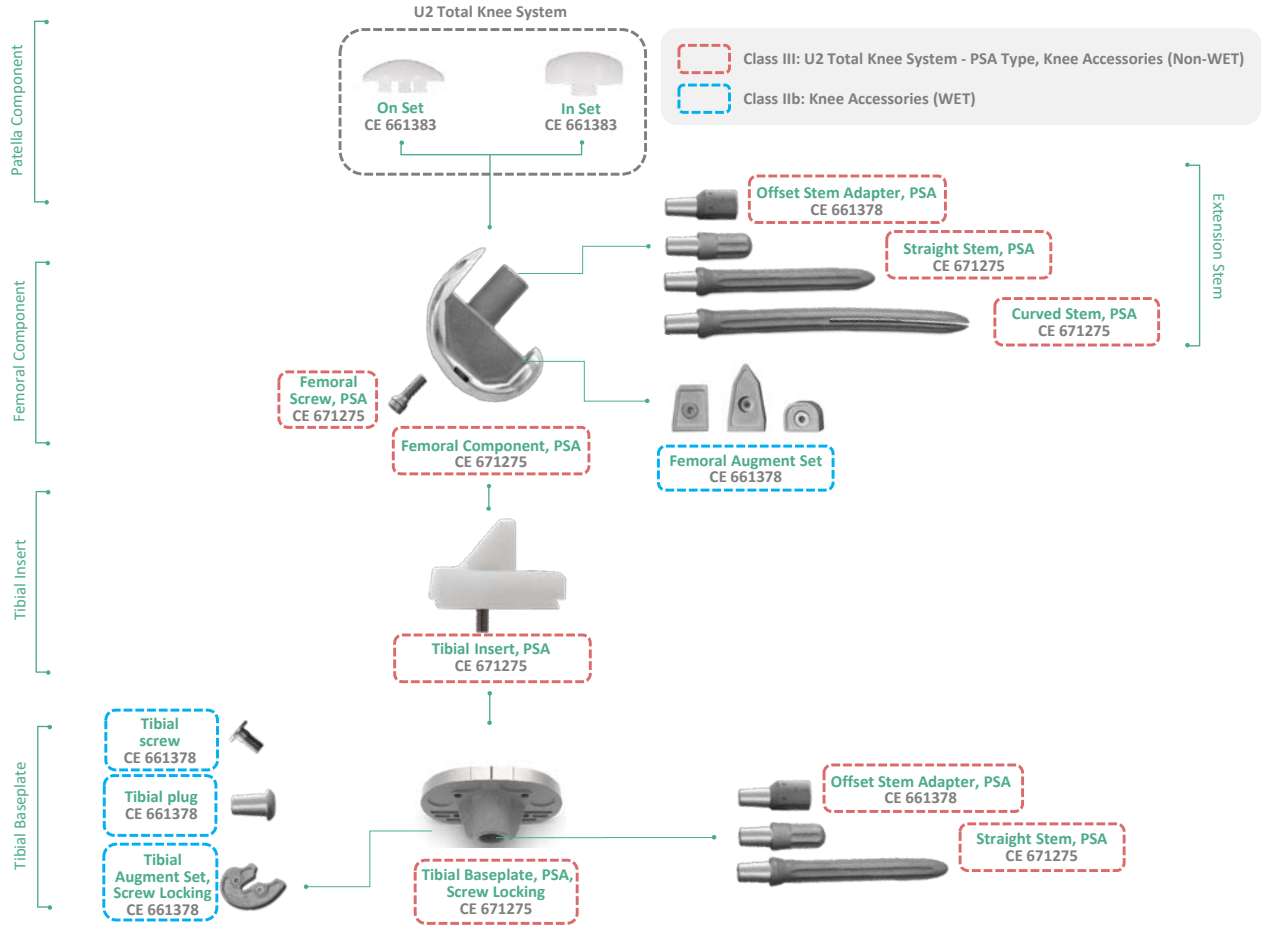
3. Device description

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

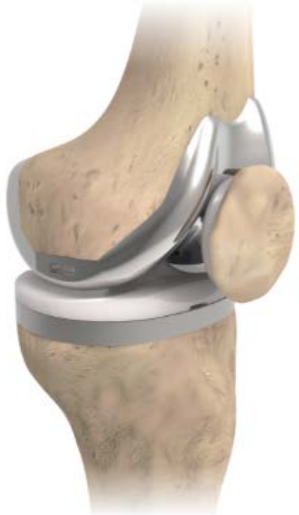
The U2 Total Knee System – PSA Type is used for revision total knee replacement. It can be used with various augments and extension stem options to manage soft tissue and bone defects, allowing surgeons the possibility for an optimal solution for each individual patient. An overview is described in picture below.


a metal femoral component to replace the end of the thigh bone
a plastic tibial insert to replace the cartilage between the thigh bone and the shin bone
a plastic patella to replace the knee cap
a metal tibial baseplate to replace the top of the shin bone
If your bone are insufficient, your doctor may use accessories, such as augment and extension stem

An overview of compatible device is described 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 – PSA Type.

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

The U2 Total Knee System – PSA Type 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. The bone surfaces where the thigh bone, shin bone and knee cap meet are covered with cartilage, which helps to cushion the knee and keep it running smoothly. When all parts of the knee are working together, the knee operates smoothly to flex and extend the lower leg. However, the knee is diseased, degenerated, or experiences an injury, its natural balance and operation may be disrupted causing pain, weakness or other medical challenges.

3.4. Description of accessories

Accessories will help your surgery proceed smoothly. If your shin bone or thigh bone is insufficient, your doctor may use augments or extension stems. 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:

Item	Possible risks and side effects	How often each risk occurs (%)[a]			
		U2 Total Knee System – PSA Type[b]		Benchmark device[c]	
		General problems	Additional surgery to replace the implant	General problems	Additional surgery to replace the implant
1	Negative tissue reaction (Adverse Local Tissue Reaction)	-	-	-	No incidence rate reported
2	Joint move out of place (Dislocation)	-	-	0.24-2.7	2.04
3	Implant disconnect (Dissociation)	0.015	-	2.97	1.19
4	Broken implant (Implant Breakage)	-	-	No incidence rate reported[d]	No incidence rate reported[d]
5	Unstable joint (Instability)	1.8	-	0.48-4.92	0.27-5.23
6	Loose implant (Loosening)	-	0.9-1.8	1.36-19.67	1.63-8.33
7	Misalignment (Malalignment)	-	-	1.19	0.27
8	Bone loss around implant (Osteolysis)	0.9	-	3.03	0.88
9	Bone break near implant (Periprosthetic Fracture)	-	-	1.08-8.2	0.24-0.82

Item	Possible risks and side effects	How often each risk occurs (%)[a]			
		U2 Total Knee System – PSA Type[b]		Benchmark device[c]	
		General problems	Additional surgery to replace the implant	General problems	Additional surgery to replace the implant
10	Implant wear (Wear)	-	-	2.7	No incidence rate reported[d]
11	Bone break (Fracture)	-	-	0.24-0.72	1.08
12	Bruise (Hematoma)	-	-	0.96-3.28	-
13	Infection	2.7	9	0.48-7.41	1.35-6.25
14	Nerve problem (Neurological Complication)	-	-	0.24	-
15	Implant noise (Noise)	-	-	0.24	No incidence rate reported[d]
16	Pain	6.3	1.8	1.08-2.27	0.6-1.33
17	Muscle, tendon, or ligament problem (Soft Tissue Complication)	1.8	-	0.24-8.2	0.65
18	Stiff joint (Stiffness)	1.8	-	0.24-5.53	1.92-2.22
19	Surgery-related issue (Surgical Complication)	-	-	1.35-8.51	-
20	Swelling	-	-	No incidence rate reported[d]	No incidence rate reported[d]
21	Blood clot (Thrombosis)	-	-	1.2-11.76	-
22	Trauma	-	-	-	No incidence rate reported[d]
23	Wound problem (Wound Complication)	-	-	0.24-1.98	-
24	Other problems	0.9	4.8	0.48-5.41	-

[a] Many things can affect the chance of problems, including but not limited to product design, how the surgery is performed, and the patient's health condition.
[b] This information is based on patient follow-up studies (PMCF), medical articles, doctor experience, and safety monitoring after the product is on the market.
[c] This information is based on medical articles and doctor experience.
[d] This side effect is identified form safety monitoring without frequency reported.

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 – PSA Type 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 amount of activities such as sports (football, running, muscle strain, etc.) that will place too much stress on the knee joint. 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 special conditions like the description of contraindications, such

as infection related to joint pain close to the surgical site, fever, etc.

- Regular X-rays shall be taken. To evaluate if the implant moves, loose, bend, fracture or the cement or bone loss. If one of these conditions occur, please pay attention and think about revision surgery.

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 to:

- 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.
- Damage 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), 13,264 sets of U2 Total Knee System – PSA Type 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.

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

PMCF Studies

Post-market clinical follow-up has been conducted for the U2 Total Knee System – PSA Type. A total of 111 knees were enrolled in the study.

Revision total knee replacement	
Cases	Total: 111 knees
Follow-up	2.7 years (range from 0.1 to 9.3)
Survival Outcomes	82.2% at 5 years follow-up

Clinical Outcomes	Knee Society Score – Knee Score: 85.5 points
	Knee Society Score – Function Score: 62.2 points
	Oxford Knee Score: 40.0 points
Complication	- Pain (6.3%) - Infection (2.7%) - Weakness (1.8%) - Instability (1.8%) - Stiffness (1.8%) - Osteolysis (0.9%) - Not specified (0.9%)
Revision	- Infection (9%) - Aseptic loosening (1.8%) - Pain (1.8%) - Mechanical loosening (0.9%)

Clinical performance conclusions

In the clinical study to support the device, the table below shows the scores for clinical outcomes:

Clinical outcomes	**Scores**
Knee Society Score	80 to 100: excellent 70 to 79: good 60 to 69: fair <60: poor
Oxford Knee Score	42 to 48: excellent 34 to 41: good 27 to 33: fair <27: poor

The performance of the device was evaluated and summarized below.

The declared lifetime of the U2 Total Knee System – PSA Type is 10 years, where average Knee Society Score and Oxford Knee Score are fair to excellent for revision total knee replacement. The expected survival rate for the revision total knee replacement is above 82%, meet the state-of-the-art.

Total knee replacement				
Revision	**Items to evaluate**		**What we expected**	**Clinical results**
	Performance	Knee Society Score: Knee	fair to excellent (average ≥ 60points)	excellent (85.5 points)
		Knee Society Score: Function	fair to excellent (average ≥ 60 points)	fair (62.2 points)

		Oxford Knee Score	fair to excellent (average ≥ 27 points)	good (40.0 points)
		Survival rate 10 years	≥ 82%	82.2% (5 years)*
* Post-market clinical follow-up plan (UOC-UPD-PL-17017) is prepared for 10 years follow-up. Currently, post-market clinical follow-up is performed continually.				

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.

Complications or adverse events	**Number of knees with complications or adverse events out of the total number of knees in the study**	**Percent (%) of patients who had this adverse event**
Pain	7 out of 111	6.3%
Infection	3 out of 111	2.7%
Weakness	2 out of 111	1.8%
Instability	2 out of 111	1.8%
Stiffness	2 out of 111	1.8%
Osteolysis	1 out of 111	0.9%
Not specified	1 out of 111	0.9%

In conclusion, the study data indicates that, U2 Total Knee System – PSA Type, has achieved the clinical performance, which used in skeletally mature patients requiring revision 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 to:

- Nonsurgical treatment:
  - Pharmacological treatment
  - Non-pharmacological
- Other surgical treatment:
  - arthroscopic debridement;
  - different type joint replacement;
  - internal fixation;
  - open debridement;

- polyethylene exchange;
- osteosynthesis;
- bone cement treatment.

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 – PSA Type, 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 – PSA Type, 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	26-08-2025	First issue.	☒Yes Validation language: English Note: The SSCP has been approved for the PSA knee accessories (including augment, plug and screw) only. ☐No
1	09-15-2025	Final NB approval extended to include the U2 Total Knee System – PSA Type.	☒Yes Validation language: English ☐ No
2	26-12-2025	Annually update.	☒Yes Validation language: English ☐ No