Summary of safety and clinical performance
(SSCP)

Intended for Patients

[U2 Hip Stem Cemented, U2 Centralizer, Cement Restrictor Full PE and I Type]

[English]

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Rev. 1

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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.

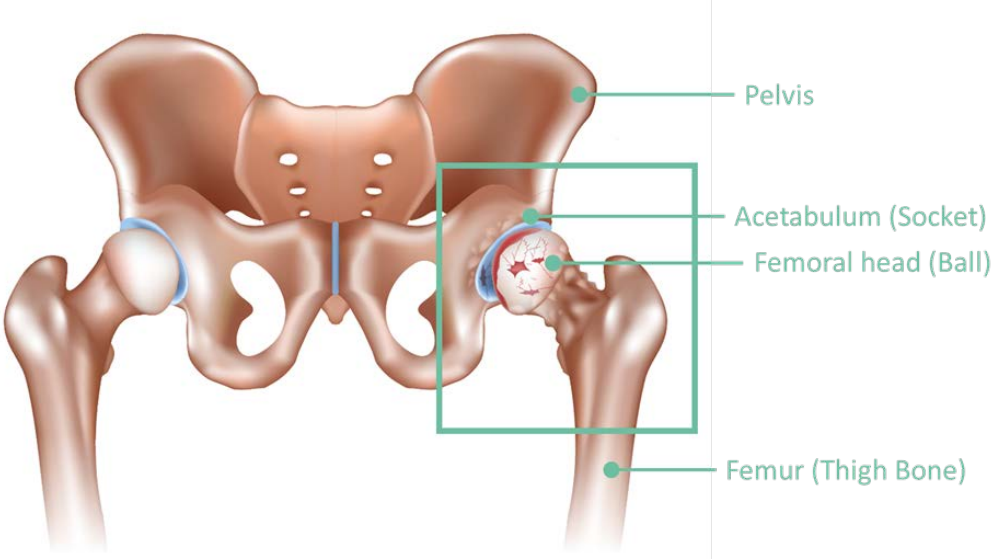
1. Device identification and general information

Device Trade Name and Model Number	United Hip System – U2 Hip Stem Cemented (1104-5223~5267) – U2 Hip Stem Centralizer (1904-5010~5018) – Cement Restrictor, Full type (1905-7007~7016) – Cement Restrictor, I type (1907-1008~1018)
Basic UDI-DI	471987216TD-III-009-1T7 (U2 Hip Stem) 471987216TD-IIb-018-15Y (U2 Hip Stem Centralizer) 471987216TD-IIb-018-262 (Cement Restrictor, Full PE) 471987216TD-IIb-018-364 (Cement Restrictor, I type)
Manufacturer	United Orthopedic Corporation
Address	No. 16, Luke 1st Rd. Luzhu Dist. Kaohsiung City, 82151, Taiwan
First Year of CE Certificate	2005 U2 Hip Stem Cemented 2001 U2 Hip Stem Centralizer, Cement Restrictor, Full PE and I Type

2. Intended use of the device

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

This document is to help you know more about the “U2 Hip Stem Cemented”, “U2 Hip Stem Centralizer”, “Cement Restrictor, Full PE and I Type”. If your hip joint is damaged by arthritis, the cartilage and bone of the hip joint become worn out. It may get hard to move and cause pain over time. Hemi hip arthroplasty is one of the treatment methods. Hip arthroplasty is intended to enhance function and mobility and reduce pain in daily activities. In this surgery, the doctor removes the damaged areas and replaces them with artificial implants. If you want to know more about your hip joint, please check the picture below. The hip consists of ball, thigh bone and pelvis.



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

U2 Hip Stem Cemented can be used in skeletally mature patients with hip pain and disability due to:

- A loss of bone and/or cartilage in the hip joint. It may cause by non-inflammatory disease or autoimmune, and inflammatory disease attack the joints.
- Treatment of bone nonunion, such as femoral neck and trochanteric fractures, involve the proximal femur with the head. It is impossible to deal with by other techniques.

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

Your doctor may decide that primary hemiarthroplasty is not suitable for you if:

- You currently have hip joint infections.
- Your bone is not strong enough.
- Your joint tissue is not stable.
- Your skeleton is not mature.

3. Device description

3.1. What is the “U2 Hip Stem Cemented”, “U2 Hip Stem Centralizer”, “Cement Restrictor, Full PE and I Type”? (Device description)

The “U2 Hip Stem Cemented”, “U2 Hip Stem Centralizer”, “Cement Restrictor, Full PE and I Type” is used for primary hemiarthroplasty. Figure 1 shows an overview of it.

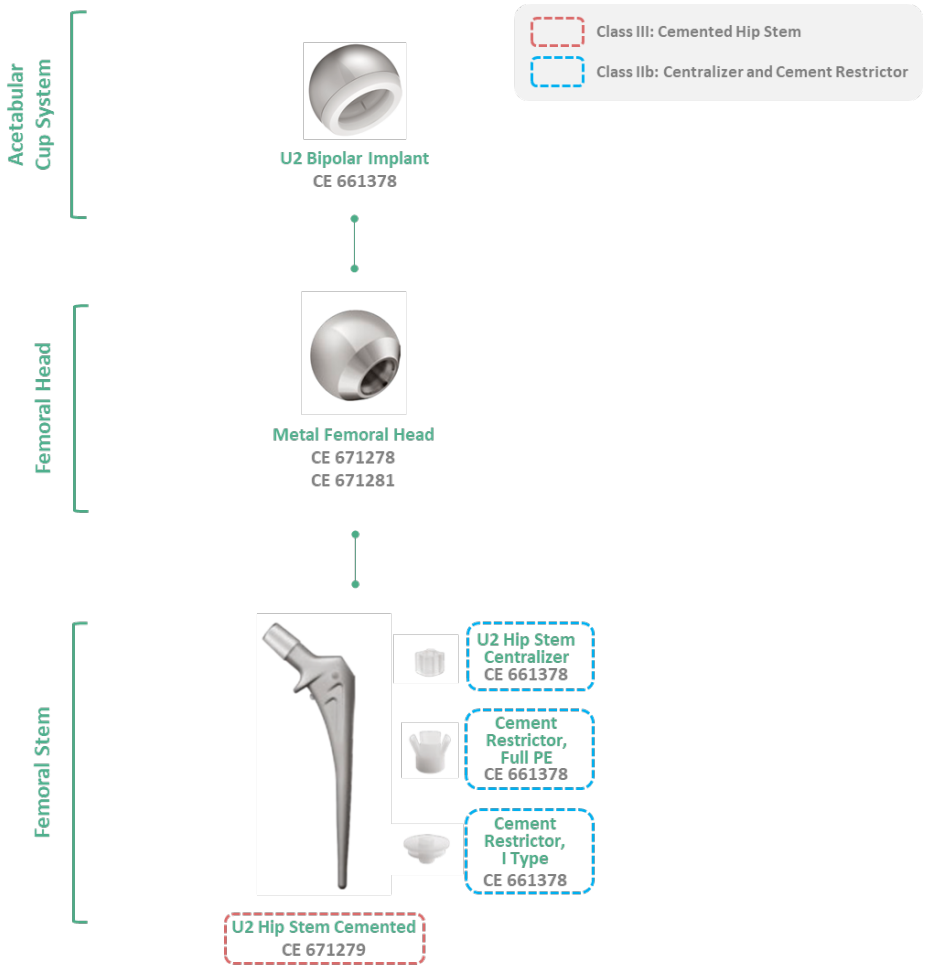
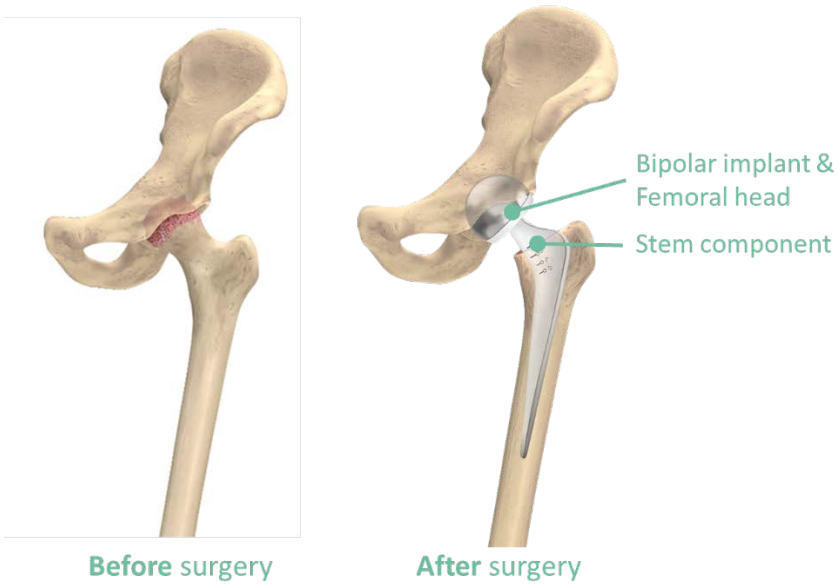


Figure 1. The compatible components for the “U2 Hip Stem Cemented”, “U2 Hip Stem Centralizer”, “Cement Restrictor, Full PE and I Type”.

If you received the Primary Hemiarthroplasty, 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 Hip Stem Cemented", "U2 Hip Stem Centralizer", "Cement Restrictor, Full PE and I Type".

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

The "U2 Hip Stem Cemented", "U2 Hip Stem Centralizer", "Cement Restrictor, Full PE and I Type" are intended to achieve what your hip work. The hip is a ball-and-socket joint. The ball is on the top of the thigh bone (femur) named the femoral head. The socket is a hollow part of the pelvis called the acetabulum. The ball is controlled by muscles, and stabilized by tendons[1] and ligaments[2]. The structures that surround the hip joint allow for hip movement and rotation.

When the hip is diseased or injured, it causes disrupted of natural balance and function. It potentially causes pain, limits mobility, or creates other medical challenges.

3.4. Description of accessories

Accessories will smooth your surgery proceed. The hip instruments will used 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[3]. This standard is the risk management specified 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 primary hemiarthroplasty. Included but are not limited to:

Item	Possible risks and side effects	How often each risk occurs (%)[a]			
		U2 Hip Stem Cemented[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[d]	0.67
2	Metal rust (Corrosion)	-	-	-	No incidence rate reported[d]
3	Broken implant (Implant breakage)	-	-	-	No incidence rate reported[d]
4	Loose implant (Loosening)	4.8	4.8	0.04-2.44	0.15-3.42

[1] Tendons: connect the muscle to the bone.
[2] Ligaments: connect bones to bones
[3] ISO 14971: Medical devices – Application of risk management to medical devices.

Item	Possible risks and side effects	How often each risk occurs (%)[a]			
		U2 Hip Stem Cemented[b]		Benchmark device[c]	
		General problems	Additional surgery to replace the implant	General problems	Additional surgery to replace the implant
5	Bone break near implant (Periprosthetic fracture)	-	-	0.32-3.65	0.03-3.6
6	Moving downwards (Subsidence)	-	-	13.57	No incidence rate reported[d]
7	Broken bone (Fracture)	-	-	0.23-0.75	No incidence rate reported[d]
8	Bruise (Hematoma)	-	-	0.47-6	0.24
9	Infection	-	-	0.38-7.33	0.7-3.33
10	Mental health condition	-	-	No incidence rate reported[d]	-
11	Pain	-	4.8	-	No incidence rate reported[d]
12	Muscle, tendon, or ligament problem (Soft tissue complication)	-	-	No incidence rate reported[d]	0.18
13	Surgery-related issue (Surgical complication)	-	-	0.5	-
14	Blood clot (Thrombosis)	-	-	0.27-2.94	-
15	Injury (Trauma)	-	-	-	No incidence rate reported[d]
16	Wound problem (Wound complication)	-	-	0.76-6	3.33
17	Other problems	-	4.8	0.49-2	0.08-1.44

[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)

- To keeping your quality of life, do not have a large amount of activities, such as sports like running, or muscle strain, etc. It will place too much stress on the hip joint. Obesity may produce loads on the hip joint. Your artificial hip joint may fail and not work if placed too much stress on it.
- For those not recommended activities and work after surgery, please follow your doctor's advice and physical therapy schedule. Your doctor will give you instructions based on you and your hip implant.
- Inform your doctor if you have 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 moves, 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.

- "U2 Hip Stem cemented" is "MR Conditional," which means you should only receive an Magnetic Resonance Imaging scan under certain conditions. Metal implants may interact with an Magnetic Resonance Imaging scanner. It may also cause heating or damage to the tissue around the implant. The metal can distort the image taken by the Magnetic Resonance Imaging scanner. You should let your doctor know you have an implant prior to receiving an Magnetic Resonance Imaging scan.

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 for a change in the way the device is used.
- Exchange of device.
- Damage of device.
- Retrofit by purchaser.
- Advice on the use of the device.
- Advice follow-up of patients, users or others.
- Recall of device.

Until now (the date issued of this document), numerous sets of U2 Hip Stem Cemented have been sold to the worldwide. The volume of sales of the products are summarized below. No field safety corrective action (recall) reported was released.

Product Name	The Volume of Sales (piece)
U2 Hip Stem Cemented	50,570
U2 Hip Stem Centralizer	3,131
Cement Restrictor Full PE	39,131
Cement Restrictor Full PE and I Type	2,510

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

The Effective Group

Post-market clinical follow-up has been conducted for the "U2 Hip Stem Cemented", "U2 Hip Stem Centralizer", "Cement Restrictor, Full PE and I Type".

No relevant information in post-market clinical follow-up studies are currently available in “U2 Hip Stem Cemented”, “U2 Hip Stem Centralizer”, “Cement Restrictor, Full PE and I Type”. United conducting the post-market clinical follow-up study at multiple clinical study sites.

Clinical performance conclusions

To quantify the clinical outcome of primary hemiarthroplasty improvement, the widely used functional score Oxford Hip Score is used to evaluate pain and function of joint. Survival rate indicates the percentage of implants that remain revision-free. In the clinical study to support the device, the scores for clinical outcomes are described below:

Clinical outcomes	Scores
Oxford Hip Score	42 to 48: excellent 34 to 41: good 27 to 33: fair <27: poor

The performance of the subject device was evaluated and summarized below.

The declared lifetime of subject device is 10 years. United will continue to collect and analyze relevant information of functional score and survival rate; then update the data in the next review. The expected survival rate for the primary hemiarthroplasty is over 81%, respectively to meet the state-of-the-art.

Primary Hemiarthroplasty				
Primary	**Items to evaluate**		**What we expected**	**Clinical results**
	Performance	Oxford Hip Score	good to excellent (average ≥ 34 points)	excellent (44.3 points)
		Survival rate 10 years	≥ 81%	95.2%

Clinical safety conclusions

In the clinical study to support the device, the safety of the device was evaluated based upon adverse event. The complications or adverse events were reported and summarized below.

Product	**Complications or adverse events**	**Number of hips with complications or adverse event out of the total number of hips in the study**	**Percent (%) of patients who had this adverse event**
U2 Hip Stem Cemented	Loosening	1 out of 21	4.8%
	Pain	1 out of 21	4.8%
	Other	1 out of 21	4.8%

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 hip. The alternative treatments may include but not limited to:

- Nonsurgical treatments:
  - non-pharmacological treatments;
  - pharmacological treatments;
  - cell therapy.
- Other surgical treatments:
  - joint aspiration, joint distraction, joint lavage
  - arthroscopic debridement;
  - cartilage repair technique;
  - internal fixation;
  - different type joint replacement.

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

If you are advised to treat with primary hemiarthroplasty and implant the “U2 Hip Stem Cemented”, “U2 Hip Stem Centralizer”, “Cement Restrictor, Full PE and I Type”, your surgery will be performed by certified Orthopedist.

8. More information

This document gives you information about your treatment choices. It is not intended to replace advice from a doctor. If you have any further questions about the “U2 Hip Stem Cemented”, “U2 Hip Stem Centralizer”, “Cement Restrictor, Full PE and I 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	23-05-2025	First issue.	☒Yes Validation language: English Note: The SSCP has been approved for the restrictors and centralizers only. ☐No

1	23-12-2025	Annually update.	☒Yes Validation language: English Note: The SSCP has been approved for the restrictors and centralizers only. ☐No