Summary of safety and clinical performance
(SSCP)

Intended for Patients

[United Hip System - GTF II Stem, U2 Hip Stem Centralizer and Cement Restrictor, Full PE]

[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.

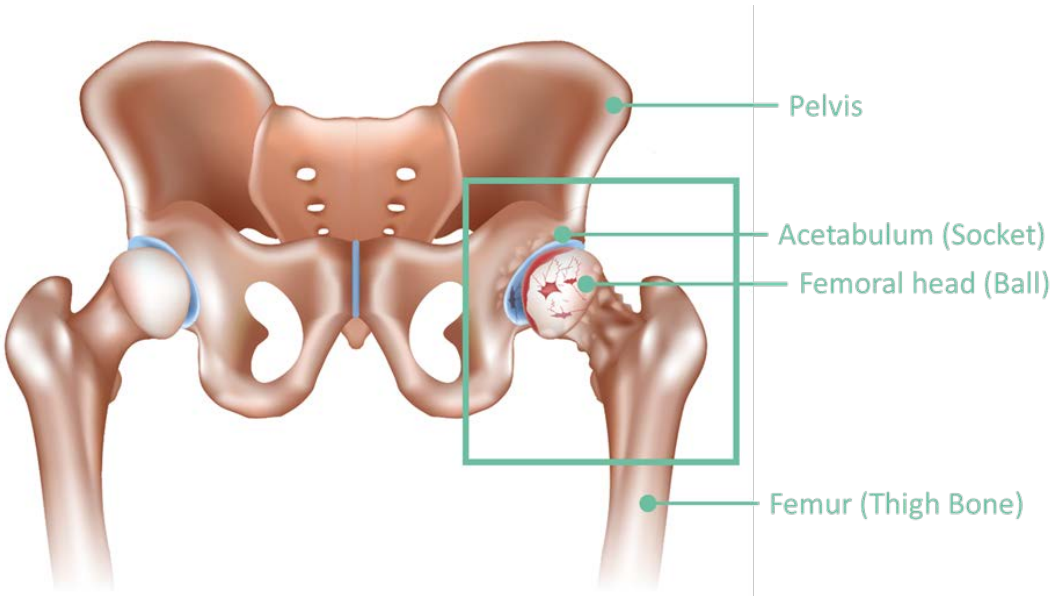
1. Device identification and general information

Device Trade Name and Model Number	United Hip System – GTF II Stem (1108-3041~3053, 1108-5041~5053) – U2 Hip Stem Centralizer (1904-5010~5018) – Cement Restrictor, Full PE (1905-7007~7016)
Basic UDI-DI	471987216TD-III-009-3TB (GTF II Stem) 471987216TD-IIb-018-15Y (U2 Hip Stem Centralizer) 471987216TD-IIb-018-262 (Cement Restrictor, Full PE)
Manufacturer	United Orthopedic Corporation
Address	No. 16, Luke 1st Rd. Luzhu Dist. Kaohsiung City, 82151, Taiwan
First Year of CE Certificate	2013 GTF II Stem 2001 U2 Hip Stem Centralizer and Cement Restrictor, Full PE

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 “GTF II Stem”, “U2 Hip Stem Centralizer” and “Cement Restrictor, Full PE”. 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. Total/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)

"GTF II Stem", "U2 Hip Stem Centralizer" and "Cement Restrictor, Full PE" Hip Stem 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 total/hemi hip arthroplasty 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 GTF II Stem? (Device description)

The "GTF II Stem", "U2 Hip Stem Centralizer" and "Cement Restrictor, Full PE" are used for total/hemi hip arthroplasty. Figure 1 shows an overview of it.

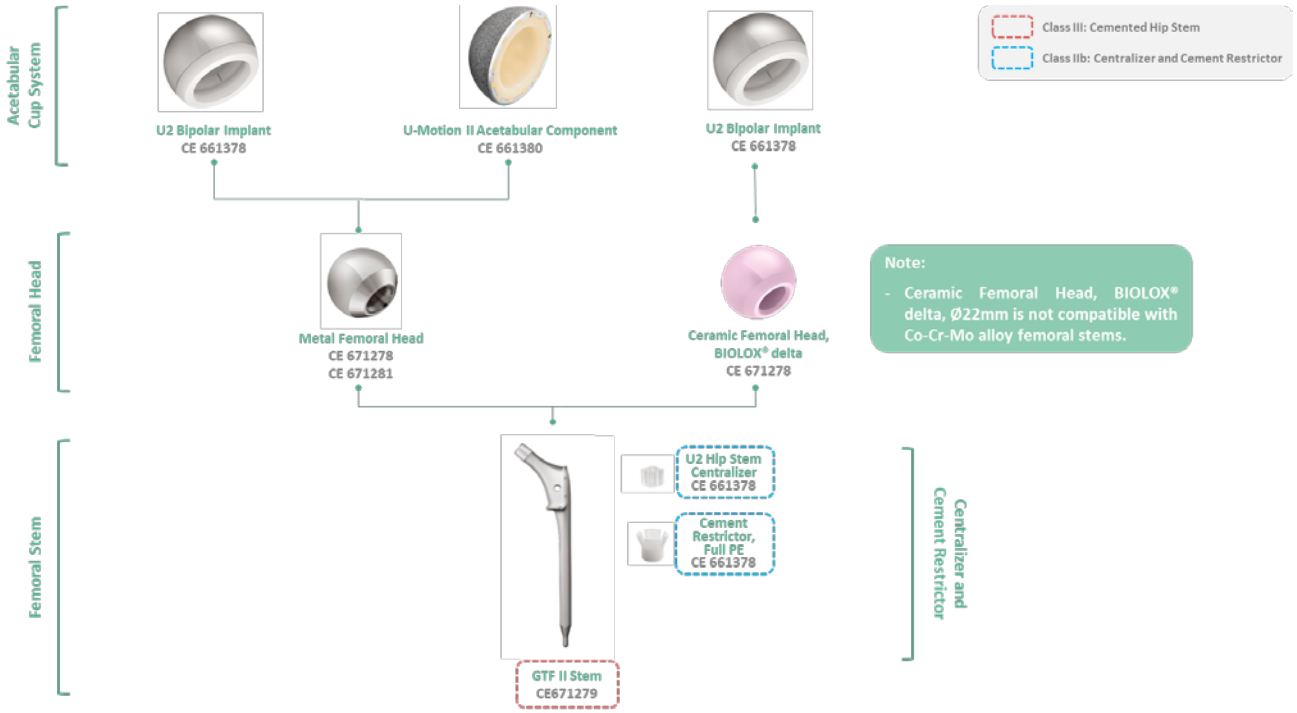
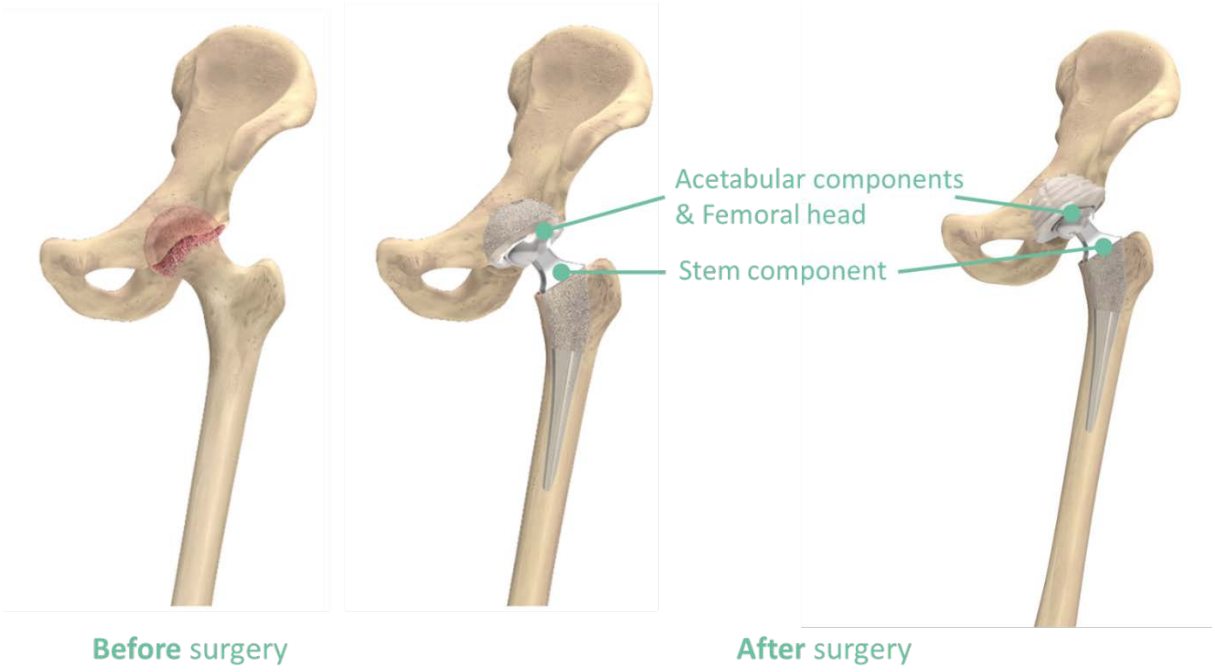
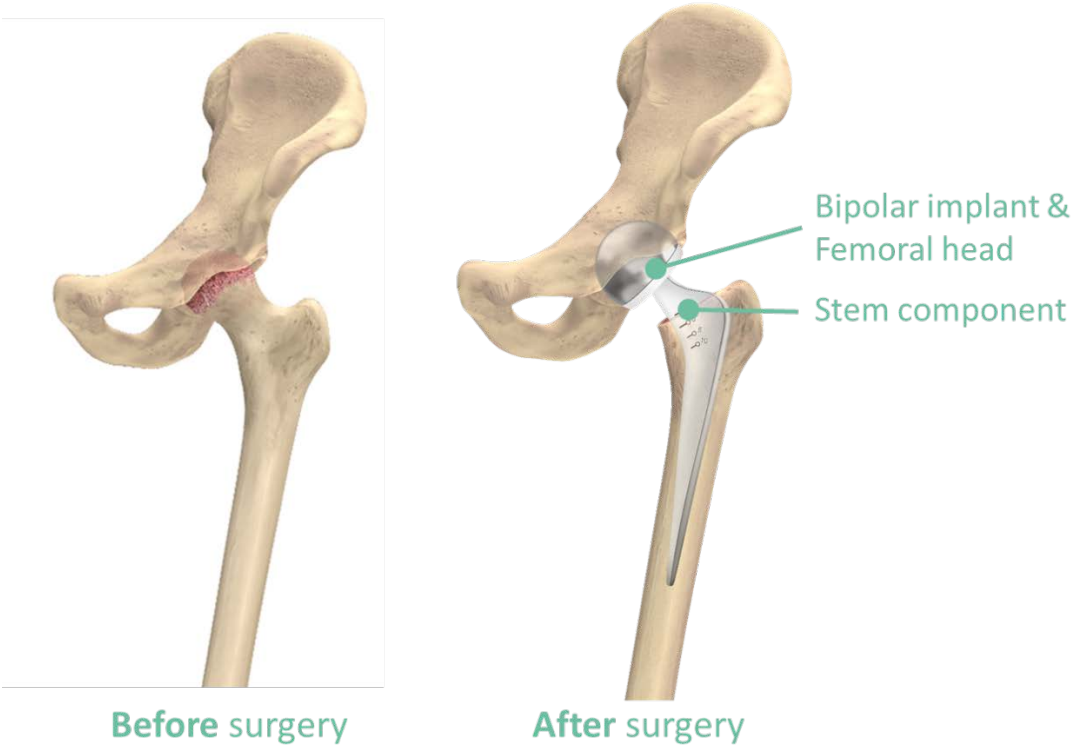


Figure 1. The compatible components for the "GTF II Stem", "U2 Hip Stem Centralizer" and "Cement Restrictor, Full PE".

If you received the Total Hip Arthroplasty, the expected consequence will be the picture shown below:



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 “GTF II Stem”, “U2 Hip Stem Centralizer” and “Cement Restrictor, Full PE”.

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

The “GTF II Stem”, “U2 Hip Stem Centralizer” and “Cement Restrictor, Full PE” 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 be 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 Total Hip Arthroplasty/Hemiarthroplasty. Included but are not limited to:

Item	Possible risks and side effects	How often each risk occurs (%)[a]			
		GTF II Stem[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)	-	-	-	0.67
2	Loose implant (Loosening)	-	-	0.04-2.44	0.15-3.42
3	Bone break near implant (Periprosthetic fracture)	-	-	0.32-3.65	0.03-3.6
4	Moving downwards (Subsidence)	-	-	13.57	-

[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]			
		GTF II Stem[b]		Benchmark device[c]	
		General problems	Additional surgery to replace the implant	General problems	Additional surgery to replace the implant
5	Broken bone (Fracture)	-	-	0.23-0.68	-
6	Bruise (Hematoma)	-	-	0.47-6	0.24
7	Infection	-	-	0.38-7.33	0.7-3.33
8	Muscle, tendon, or ligament problem (Soft tissue complication)	-	-	-	0.18
9	Surgery-related issue (Surgical complication)	-	-	0.5	-
10	Blood clot (Thrombosis)	-	-	0.27-2.94	-
11	Wound problem (Wound complication)	-	-	0.76-6	3.33
12	Other problems	-	-	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.
- "GTF II Stem" 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 the "GTF II Stem", "U2 Hip Stem Centralizer" and "Cement Restrictor, Full PE" have been sold 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)
GTF II Stem	3,366
U2 Hip Stem Centralizer	3,131
Cement Restrictor, Full PE	39,131

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

The Effective Group

Post-market clinical follow-up has been conducted for the "GTF II Stem", "U2 Hip Stem Centralizer" and "Cement Restrictor, Full PE". The post-market clinical follow-up results are summarized in the table below. To quantify the clinical outcome of hip arthroplasty improvement, two widely used functional score, Harris Hip Score and Oxford Hip Score are used to evaluate pain, function, deformity, and range of motion. Survival rate indicates the percentage of implants that remain revision-free.

Devices	GTF II Stem collocated with U2 Hip Stem Centralizer and Cement Restrictor, Full PE
Primary Hemiarthroplasty	
Cases	11 hips
Follow-up	3 years (range from 1.1 to 5.7 years)

Survival Outcomes		100% at 5 years follow-up*
Clinical Outcomes	**Harris Hip Score**	80.9 points
	Oxford Hip Score	29.3 points
Complication		No complication was reported
Revision		No revision was reported
Primary Total Hip Arthroplasty		
Cases		3 hips
Follow-up		3.4 years (range from 2.2 to 4.6 years)
Survival Outcomes		100% at 3 years follow-up*
Clinical Outcomes	**Oxford Hip Score**	24.3 points
Complication		No complication was reported
Revision		No revision was reported
Revision Total Hip Arthroplasty		
Cases		3 hips
Follow-up		2.6 years (range from 1.4 to 4.7 years)
Survival Outcomes		100% at 3 years follow-up*
Clinical Outcomes	**Oxford Hip Score**	21.3 points
Complication		No complication was reported
Revision		No revision was reported

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

Clinical performance conclusions

. In the clinical study to support the device, the scores for clinical outcomes are described below:

Clinical outcomes	Scores
Harris Hip Score	90 to 100: excellent 80 to 89: good 70 to 79: fair <70: poor
Oxford Hip 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 GTF II Stem, U2 Hip Stem Centralizer and Cement Restrictor, Full PE 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.

Hip replacement				
Primary Hemiarthroplasty	**Items to evaluate**		**What we expected**	**Clinical results**
	Performance	Harris Hip Score	good to excellent (average ≥ 80 points)	good (80.9 points)
		Oxford Hip Score	good to excellent (average ≥ 34 points)	fair (29.3 points)**
		Survival rate 10 years	≥ 81%	100% (5 year) *
Primary Total Hip Arthroplasty	**Items to evaluate**		**What we expected**	**Clinical results**
	Performance	Harris Hip Score	good to excellent (average ≥ 80 points)	No relevant information*
		Oxford Hip Score	good to excellent (average ≥ 34 points)	poor (24.3 points)**
		Survival rate 10 years	≥ 95%	100% (3 year) *
Revision Total Hip Arthroplasty	**Items to evaluate**		**What we expected**	**Clinical results**
	Performance	Harris Hip Score	fair to excellent (average ≥ 70 points)	No relevant information*
		Oxford Hip Score	fair to excellent (average ≥ 27 points)	poor (21.3 points)**
		Survival rate 10 years	≥ 85%	100% (3 year) *
*The post-market clinical follow-up is continued to achieve maximum follow-up of 10 years based on our post-market clinical follow-up plan to confirm its safety and performance. **The data were further reviewed by external expert to determine its acceptability, and were acceptable after review.				

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**	**Percent (%) of patients who had this adverse event**

		number of hips in the study	
GTF II Stem	No complication was reported.		

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 hip arthroplasty and implant the "GTF II Stem", "U2 Hip Stem Centralizer" and "Cement Restrictor, Full PE", 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 "GTF II Stem", "U2 Hip Stem Centralizer" and "Cement Restrictor, Full PE", 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