Summary of safety and clinical performance
(SSCP)

Intended for Patients

[United Hip System
– Femoral Head and U2 Bipolar Implant]

[English]

www.unitedorthopedic.com

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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.

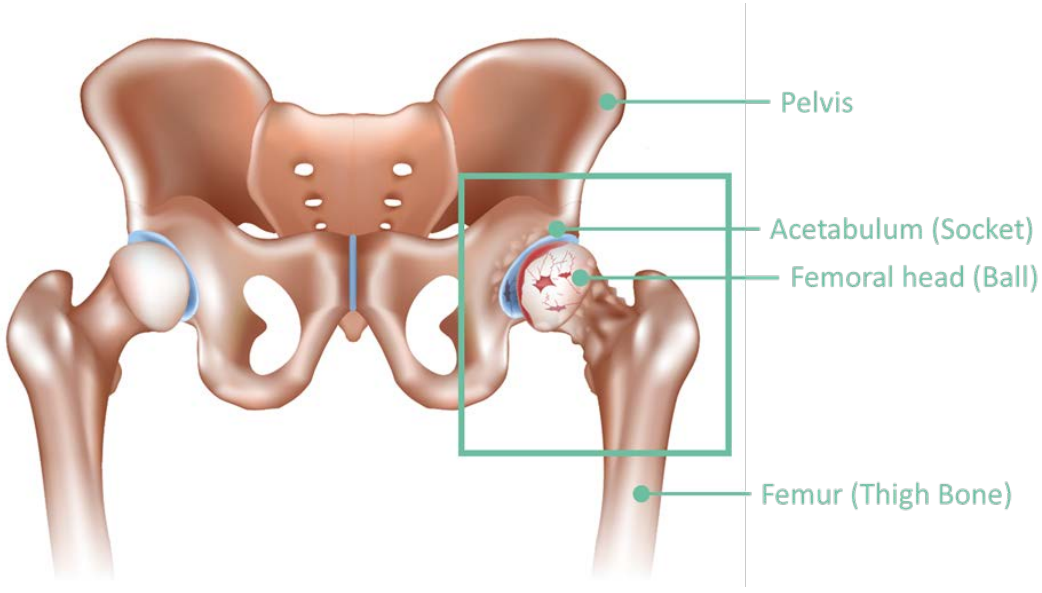
1. Device identification and general information

Device Trade Name	– U1 Hip System, Femoral Head – United Hip System, U2 Femoral Head – Ceramic Femoral Head, BIOLOX® Delta – United Hip System, U2 Bipolar Implant
Basic UDI-DI	471987216TD-III-005-1SK U1 Hip System, Femoral Head 471987216TD-III-005-2SM United Hip System, U2 Femoral Head 471987216TD-III-005-3SP Ceramic Head, BIOLOX® Delta 471987216TD-III-005-4SR United Hip System, U2 Bipolar Implant
Manufacturer	United Orthopedic Corporation
Address	No. 16, Luke 1st Rd. Luzhu Dist., Kaohsiung City 82151, Taiwan.
First Year of CE Certificate	2001 (Femoral Head) 2011 (United Hip System, U2 Bipolar Implant)

2. Intended purpose and other indications

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

This document is to help you know more about the “U1 Hip System, Femoral Head”, “United Hip System, U2 Femoral Head”, “Ceramic Femoral Head, BIOLOX® Delta” and “United Hip System, U2 Bipolar Implant”. 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 a ball, thigh bone and pelvis.



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

"U1 Hip System, Femoral Head", "United Hip System, U2 Femoral Head", "Ceramic Femoral Head, BIOLOX® Delta" and "United Hip System, U2 Bipolar Implant" 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.
- Bone tissue in the thigh bone near the hip joint dies because of a lack of blood supply.
- The ball at the top of the thigh bone doesn't fit well into the socket of the pelvis.
- Revision procedures when other treatments or devices have failed.
- Treatment of bone nonunion, such as femoral neck and trochanteric fractures, involve the proximal femur with the head. Other methods might not work as well in this case.

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

Your doctor may decide that total 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.
- You are fever before the surgery.

3. Device description

3.1. What is the "U1 Hip System, Femoral Head", "United Hip System, U2 Femoral Head", "Ceramic Femoral Head, BIOLOX® Delta" and "United Hip System, U2 Bipolar Implant"? (Device description)

"U1 Hip System, Femoral Head" and "United Hip System, U2 Femoral Head" are indicated for primary or revision Total Hip Arthroplasty or primary Hemiarthroplasty.

"Ceramic Femoral Head, BIOLOX® Delta" are indicated for primary total hip arthroplasty.

"United Hip System, U2 Bipolar Implant" is indicated for primary hemiarthroplasty.

Figure 1 shows an overview of it.

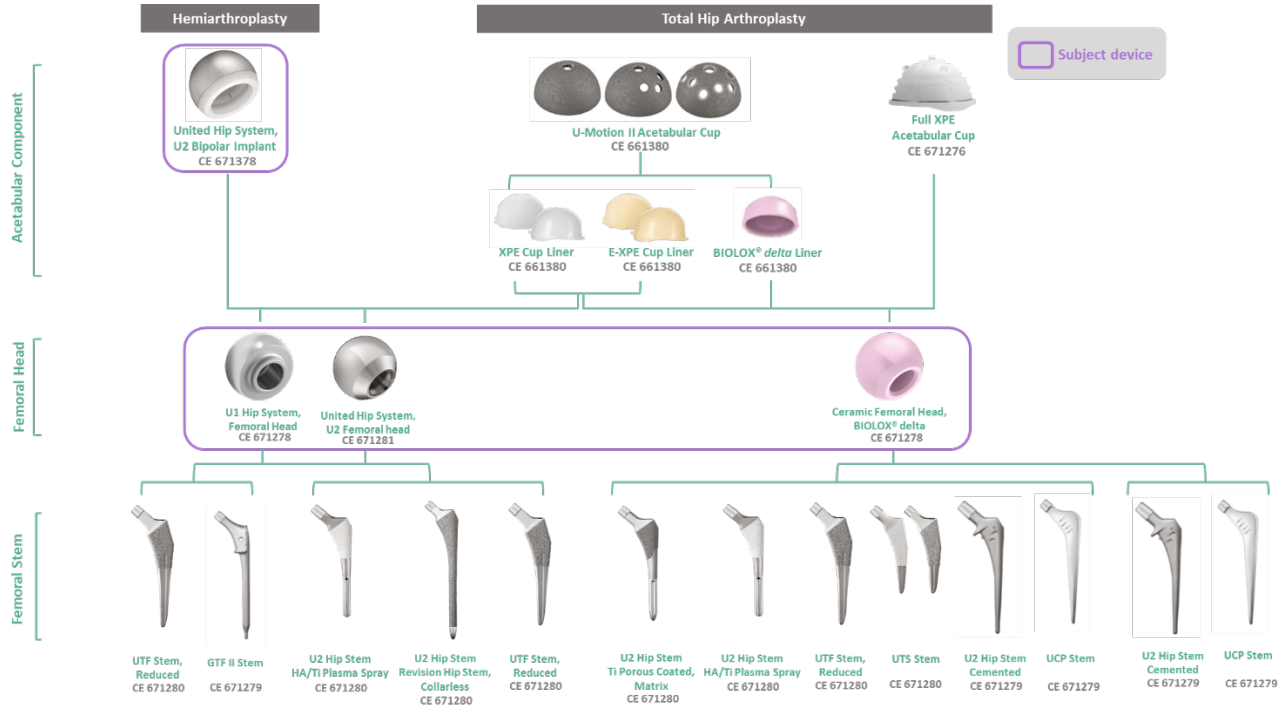
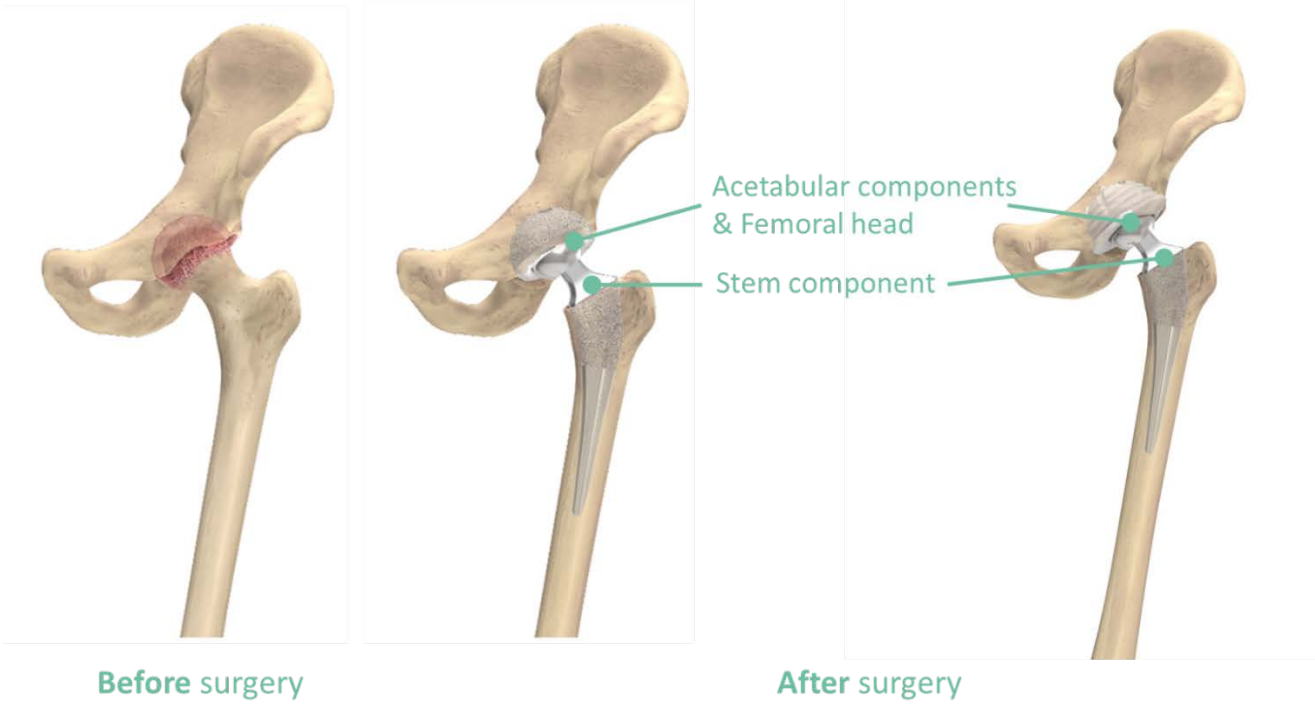
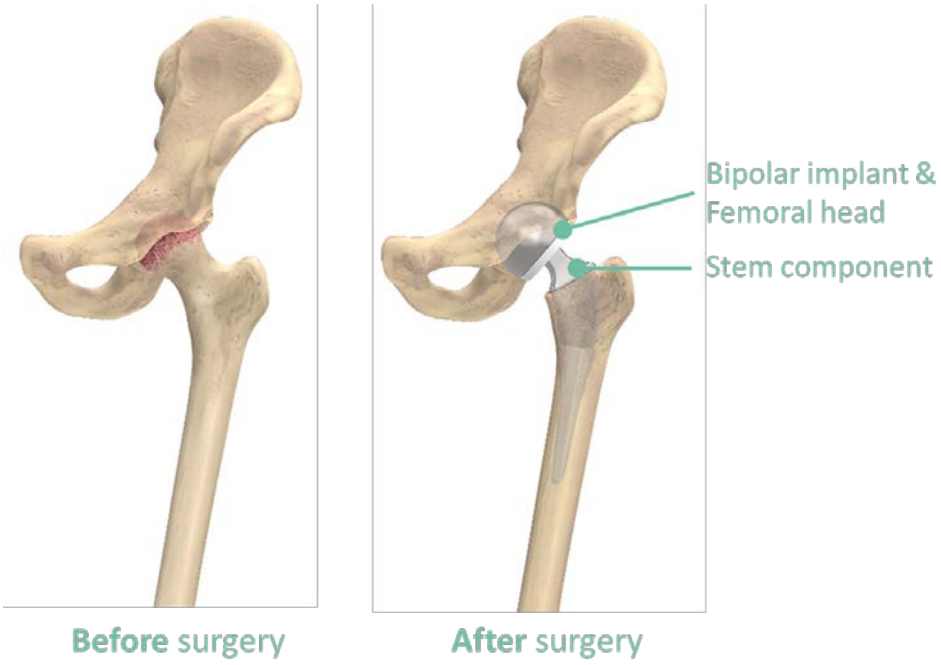


Figure 1. The compatible components for the Femoral Head and U2 Bipolar Implant.

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



If you received the hemiarthroplasty, the expected consequence will be the picture shown below:



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

None. None of medicinal substances contain in the Femoral Head and U2 Bipolar Implant.

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

"U1 Hip System, Femoral Head", "United Hip System, U2 Femoral Head", "Ceramic Femoral Head, BIOLOX® Delta" and "United Hip System, U2 Bipolar Implant" 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 process. The hip instruments will used to finish your surgery.

4. Risks and warnings

4.1. How potential risks have been controlled or managed

All the possible risks have been controlled. The risks are decreased as low as possible by following

[1] Tendons: connect the muscle to the bone.
[2] Ligaments: connect bones to bones

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 hip arthroplasty. Included but are not limited to:
Adverse events are grouped into implant-related and procedure-related categories, with general adverse events reported. The incidence rate for the subject device comes from post-market clinical follow-up reports, which show actual events with United's device. The incidence rate for the benchmark device is based on data from literatures search.

Adverse Events Reported of Femoral Head				
Adverse Event	**Risk Classification**		**Incidence Rate**	
	Implant related	**Procedure related**	**Femoral Head**	**Benchmark device**
Implant component movement	X	X	0.8% (4 out of 507)	9.42%
Particle break off from implant component	X	X	-	No incidence rate reported
Bone tissue break down	X	X	-	2.80%
Anatomical structure being out of normal alignment	X	X	0.2% (1 out of 507)	0.22%
Noise	X	X	-	3.53%
Unstable joint	X	X	-	0.56%
Negative reaction around local tissue	X	-	-	No incidence rate reported
Implant corrosion	X	-	-	No incidence rate reported
Wound localized blood collection	-	X	-	No incidence rate reported
Infection	-	X	0.2%-1.1% (1 out of 507-1 out of 92)	No incidence rate reported
Limp	-	X	1.1%-1.2% (1 out of 92-6 out of 507)	No incidence rate reported
Different leg length	-	X	1.0%-1.1% (5 out of 507-1 out of 92)	No incidence rate reported
Neurological complication	-	X	-	No incidence rate reported
Pain	-	X	3.2% (16 out of 507)	No incidence rate reported
Size mismatch	-	X	-	No incidence rate reported
Surgical complication	-	X	-	No incidence rate reported
Blood clots	-	X	-	No incidence rate reported

[3] ISO 14971: Medical devices – Application of risk management to medical devices.

Adverse Events Reported of Femoral Head				
Adverse Event	**Risk Classification**		**Incidence Rate**	
	Implant related	**Procedure related**	**Femoral Head**	**Benchmark device**
Soft tissue complication	-	X	-	No incidence rate reported
Weakness	-	X	0.2% (1 out of 507)	No incidence rate reported
Wound complication	-	X	-	No incidence rate reported
Lumbar stenosis	-	X	0.4% (2 out of 507)	No incidence rate reported

Adverse Events Reported of U2 Bipolar Implant				
Adverse Event	**Risk Classification**		**Incidence Rate**	
	Implant related	**Procedure related**	**U2 Bipolar Implant**	**Benchmark device**
Implant component movement	X	X	-	8.17%
Implant fracture	X	-	-	No incidence rate reported
Particle break off from implant component	X	X	-	9.09%
Bone tissue break down	X	X	-	No incidence rate reported
Anatomical structure being out of normal alignment	X	X	-	No incidence rate reported
Infection	-	X	-	No incidence rate reported
Neurological complication	-	X	-	No incidence rate reported
Pain	-	X	-	No incidence rate reported
Soft tissue complication	-	X	-	No incidence rate reported
Blood clots	-	X	-	No incidence rate reported
Wound complication	-	X	-	No incidence rate 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 components of United Hip System with another manufacturer's hip devices. 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 (running, or muscle strain, etc.) that will place too much stress on the hip joint. Please follow your doctor's

recommendations for weight management. 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 recommendations and physical therapy schedule. Your doctor will give you instructions based on you and your hip 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 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 decline 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.

For Femoral Heads and United Hip System, U2 Bipolar Implant

Until now (the date issued of this document), numerous sets of the Femoral Head and U2 Bipolar Implant have been sold worldwide. The table below shows the number of each product sold. No field safety corrective action (recall) reported was released.

Product Name	The Volume of Sales (piece)
U1 Hip System, Femoral Head	236,551
United Hip System, U2 Femoral Head	38,692
Ceramic Femoral Head BIOLOX® Delta	103,723
United Hip System, U2 Bipolar Implant	99,327

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

The Effective Group

Post-market clinical follow-up has been conducted for the Femoral Head and U2 Bipolar Implant.

- **United Metal Femoral Head (U1 Hip System, Femoral Head)**

Total 92 metal femoral heads with average follow-up of 2.5 years (range from 0.9 to 10) were enrolled in the study.

- **United Metal Femoral Head (United Hip System, U2 Femoral Head)**

Total 9 metal femoral heads with average follow-up of 0.9 years (range from 0.3 to 1.1) were enrolled in the study.

- **Ceramic Femoral Head BIOLOX® Delta**

Total 507 ceramic femoral heads with average follow-up of 1.7 years (range from 0.2 to 6.7) were enrolled in the study.

- **United Hip System, U2 Bipolar Implant**

Total 18 hips with average follow-up of 3.1 years (range from 1.1 to 6.0 years) were enrolled in the study.

Clinical performance conclusions

The Harris Hip Score measures both the patient's expectations and their ability to do daily activities, along with the information doctors need to assess. The Oxford Hip Score focuses on hip pain and how it affects daily and work activities, helping doctors track treatment results. The revision rate shows the percentage of people who need surgery to replace the implant. Primary total hip arthroplasty refers to the first hip replacement surgery. Revision total hip arthroplasty refers to a second (or more) surgeries to replace the hip. In the clinical study supporting the device, the table below shows the clinical outcome scores:

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 devices was evaluated and summarized below.

- **United Metal Femoral Head (U1 Hip System, Femoral Head)**

The declared lifetime of the United Metal Femoral Head is 10 years. Both average Oxford Hip Score and Harris Hip Score are good to excellent and the expected revision rate for the first total hip replacement and the hemiarthroplasty is below 4.00% and 6.00%, respectively to meet the state-of-the-art.

Hemiarthroplasty					
Primary	**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)	good (38.4 points)
	Safety	Revision rate	5 years	≤ 4%	0 %
			10 years	≤ 6%	No relevant information*
Total Hip Arthroplasty					
Primary	**Items to evaluate**			**What we expected**	**Clinical results**
	Performance	Harris Hip Score		good to excellent (average ≥ 80 points)	good (88.5 points)
		Oxford Hip Score		good to excellent (average ≥ 34 points)	excellent (44.0 points)
	Safety	Revision rate	5 years	≤ 3%	0 %
			10 years	≤ 4%	No relevant information*
Revision	**Items to evaluate**			**What we expected**	**Clinical results**
	Performance	Harris Hip Score		good to excellent (average ≥ 70points)	excellent (90.5 points)
		Oxford Hip Score		good to excellent (average ≥ 27 points)	good (45.7 points)
	Safety	Revision rate	5 years	≤ 14%	0 %
			10 years	≤ 18%	0 %

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

- **United Metal Femoral Head (United Hip System, U2 Femoral Head)**

The declared lifetime of the United Metal Femoral Head is 10 years. United Hip System, U2 Femoral head is claim equivalent to the marketed device, U1 Hip System, Femoral Head. It is considered that the clinical performance and safety of United Hip System, U2 Femoral head can be represented by U1 Hip System, Femoral Head.

Hemiarthroplasty

Primary	**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)	No relevant information*
	Safety	Revision rate	5 years	≤ 4%	No relevant information*
			10 years	≤ 6%	No relevant information*
Total Hip Arthroplasty					
Primary	**Items to evaluate**			**What we expected**	**Clinical results**
	Performance	Harris Hip Score		good to excellent (average ≥ 80 points)	excellent (98.0 points)
		Oxford Hip Score		good to excellent (average ≥ 34 points)	No relevant information*
	Safety	Revision rate	5 years	≤ 3%	No relevant information*
			10 years	≤ 4%	No relevant information*
Revision	**Items to evaluate**			**What we expected**	**Clinical results**
	Performance	Harris Hip Score		good to excellent (average ≥ 70points)	No relevant information*
		Oxford Hip Score		good to excellent (average ≥ 27 points)	No relevant information*
	Safety	Revision rate	5 years	≤ 14%	No relevant information*
			10 years	≤ 18%	No relevant information*

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

- **Ceramic Femoral Head BIOLOX® Delta**

The declared lifetime of the Ceramic Femoral Head BIOLOX® Delta is 10 years. Both average Oxford Hip Score and Harris Hip Score are excellent and the expected revision rate for the first total hip replacement is below 4.00% to meet the state-of-the-art.

Total Hip Arthroplasty					
Primary	**Items to evaluate**			**What we expected**	**Clinical results**
	Performance	Harris Hip Score		good to excellent (average ≥ 80 points)	excellent (93.8 points)
		Oxford Hip Score		good to excellent (average ≥ 34 points)	excellent (44.6 points)
	Safety	Revision rate	5 years	≤ 3%	0.5%
			10 years	≤ 4%	No relevant information*

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

- **United Hip System, U2 Bipolar Implant**

The declared lifetime of the - United Hip System, U2 Bipolar Implant is 10 years. Both average Oxford Hip Score and Harris Hip Score are good and the expected revision rate for the hemiarthroplasty is below 4 % to meet the state-of-the-art.

Hemiarthroplasty					
Primary	**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)	good (38.4 points)
	Safety	Revision rate	5 years	≤ 4%	0%*
			10 years	≤ 6%	No relevant information*

*The post-market clinical follow-up is continued to reach maximum follow-up of 10 years based on our post-market clinical follow-up 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.

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**
United Metal Femoral Head	Infection	1 out of 92	1.1%
	Limping	1 out of 92	1.1%
	Leg length discrepancy	1 out of 92	1.1%
Ceramic Femoral Head BIOLOX® Delta	Dislocation	4 out of 507	0.8%
	Claudication	6 out of 507	1.2%
	Leg length discrepancy	5 out of 507	1.0%
	Cellulitis both leg	1 out of 507	0.2%
	Head-liner impingement	1 out of 507	0.2%
	Lumbar stenosis	2 out of 507	0.4%
	Pain	16 out of 507	3.2%
	Weakness	1 out of 507	0.2%

United Hip System, U2 Bipolar Implant	No complication was reported.

In conclusion, the Femoral Head and U2 Bipolar Implant has achieved the clinical performance at 10 years after surgery, which used in skeletally mature patients requiring total hip arthroplasty and hemiarthroplasty.

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

If you are thinking about other treatments, please consult your doctor. Your doctor can give advice based on your age, general health, and the condition of your hip. Other 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 Femoral Head and U2 Bipolar Implant, 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 Femoral Head and U2 Bipolar Implant, 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	19-06-2025	First issue.	☒Yes

			Validation language: English ☐No
1	23-12-2025	Annually update.	☒Yes Validation language: English ☐No