Patient User Manual for “United U2 Total Knee System”

Intended Use

- The “United U2 Total Knee System” is intended use for primary or revision total knee replacement for enhancing function and mobility and reducing pain in daily activities in skeletally mature patients.
- The device name and catalog number of your implant can be found on your implant card. If a healthcare professional asks about your implant, please show them your implant card.
- Materials used for implant of United U2 Total Knee System:

Implant	Material description	Substances in material	Composition (% w/w)	Material weight range (g)	Material concentration range (% w/w)
Femoral component, Cemented	Co-Cr-Mo alloy (ASTM F75)	Chromium (Cr)	27-30	53.36~161.33	32.00~41.29
		Molybdenum (Mo)	5.0-7.0		
		Nickel (Ni)	≤0.5		
		Iron (Fe)	≤0.75		
		Carbon (C)	≤0.35		
		Silicon (Si)	≤1.0		
		Maganese (Mn)	≤1.0		
		Tungsten (W)	≤0.2		
		Phosphorous (P)	≤0.02		
		Sulfur (S)	≤0.01		
		Nitrogen (N)	≤0.25		
		Aluminum (Al)	≤0.1		
		Titanium (Ti)	≤0.1		
		Boron (B)	≤0.01		
		Cobalt (Co)	balance	97.91~265.69	58.71~68.00
Femoral Component, Porous Coated	Co-Cr-Mo alloy (ASTM F75)	Chromium (Cr)	27-30	57.70~174.76	32.00~41.29
		Molybdenum (Mo)	5.0-7.0		
		Nickel (Ni)	≤0.5		
		Iron (Fe)	≤0.75		
		Carbon (C)	≤0.35		
		Silicon (Si)	≤1.0		
		Maganese (Mn)	≤1.0		
		Tungsten (W)	≤0.2		
		Phosphorous (P)	≤0.02		
		Sulfur (S)	≤0.01		
		Nitrogen (N)	≤0.25		
		Aluminum (Al)	≤0.1		
		Titanium (Ti)	≤0.1		
		Boron (B)	≤0.01		
		Cobalt (Co)	balance	105.86~287.80	58.71~68.00
Femoral component, PF+	Co-Cr-Mo alloy (ASTM F75)	Chromium (Cr)	27-30	57.69~182.00	32.00~41.29
		Molybdenum (Mo)	5.0-7.0		
		Nickel (Ni)	≤0.5		
		Iron (Fe)	≤0.75		
		Carbon (C)	≤0.35		
		Silicon (Si)	≤1.0		
		Maganese (Mn)	≤1.0		

Implant	Material description	Substances in material	Composition (% w/w)	Material weight range (g)	Material concentration range (% w/w)
		Tungsten (W)	≤0.2		
		Phosphorous (P)	≤0.02		
		Sulfur (S)	≤0.01		
		Nitrogen (N)	≤0.25		
		Aluminum (Al)	≤0.1		
		Titanium (Ti)	≤0.1		
		Boron (B)	≤0.01		
		Cobalt (Co)	balance	105.84~299.74	58.71~68.00
Tibial Baseplate Cemented	Ti-6Al-4V alloy (ASTM F136)	Nitrogen (N)	≤0.05	61.59~87.61	100
		Carbon (C)	≤0.08		
		Hydrogen (H)	≤0.012		
		Iron (Fe)	≤0.25		
		Oxygen (O)	≤0.13		
		Aluminum (Al)	5.5-6.5		
		Vanadium (V)	3.5-4.5		
		Titanium (Ti)	balance		
Tibial Baseplate, CMA	Ti-6Al-4V alloy (ASTM F136)	Nitrogen (N)	≤0.05	54.52~87.92	100
		Carbon (C)	≤0.08		
		Hydrogen (H)	≤0.012		
		Iron (Fe)	≤0.25		
		Oxygen (O)	≤0.13		
		Aluminum (Al)	5.5-6.5		
		Vanadium (V)	3.5-4.5		
		Titanium (Ti)	balance		
		Hydrogen (H)	0.03		
		Nitrogen (N)	0.02		
		Silicon (Si)	0.04		
		Chloride (Cl)	0.20		
		Sodium (Na) or Magnesium (Mg)	0.50		
		Titanium (Ti)	balance		
		Aluminum (Al)	5.5-6.5		
		Vanadium (V)	3.5-4.5		
		Titanium (Ti)	balance		
Tibial Insert	UHMWPE Type 1 (ASTM F648)	Ultra High Molecular Weight Polyethylene	100	12.24~68.42	100
Patella	UHMWPE Type 1 (ASTM F648)	Ultra High Molecular Weight Polyethylene	100	2.34~7.52	100

Expected Lifetime of the Device and Follow up

The implant is designed to replace your damage knee joint and permanently in your body. The knee joint replacement surgery is the major therapy and is a safe and effective surgical procedure. Most patients have a good result but some people may have complications. Factors such as joint anatomy (size and shape), weight, activity level, medical condition, comorbidities and surgery may affect the outcomes and shorten or prolong the expected lifetime.

Lifetime is the time from implantation to removal of part (or all) of implant from your body. The expected lifetime of knee joint implant is based upon clinical data and testing designed to meet at least 10 years of simulated use. Joint replacement registries collect information of joint replacement outcomes to provide an evidence-based for safe and effective options. On the basis of the collected and analyzed information in the registries, first total joint replacement is generally 95% (95 out of 100) last more than 10 years. This means that at 10 years about 5% (5 out of 100) of patients may have had additional surgery to remove part(s). Based on the Post-Market Clinical Follow-up (PMCF) data of United U2 Total Knee System, first total joint replacement is >95% at 10 years. You can't know for sure if you'll have complications that need more surgery.

The lifetime of your hip joint replacement depends on your specific medical needs. Ask your doctor about things you can

do to help it stay good for a long time. That may include avoiding high-impact activities, such as running, as well as keeping a healthy weight. Your doctor has access to data published for your implant and will be able to provide more information based on your specific needs.

Possible side effect or risks:

The following risks have been associated with total knee joint replacement.

- Loosening, breaking, dislocation or movement of the components
- Wear debris of polyethylene components
- Urinary or genital issues
- Digestive issues
- Blood clots
- Heart attack
- Nerve damage
- Metal sensitivity reactions or particles generated may result in osteolysis or the other medical complication
- Change in mental status

Let others know about your joint replacement, as in the following situations:

- Metal implants could set off the alarm in security screening machines like the ones in airports.
- "United U2 Total Knee System" is "MR Conditional," which means you should only receive an MRI (Magnetic Resonance Imaging) scan under certain conditions. Metal implants may interact with an MRI scanner. It may also cause heating or damage to the tissue around the implant. The metal can distort the image taken by the MRI scanner. You should let your doctor know you have an implant prior to receiving an MRI scan.
- Make health care providers (doctors, dentists, etc.) aware of your implant as it may affect their choices for your care.
- Additional information can be found in the European database on medical devices (EUDAMED): https://ec.europa.eu/tools/eudamed

Symbol glossary used in "United" Implant Card

Patient Name or patient ID	Date of implantation	Name and Address of the implanting healthcare institution/provider
REF Catalogue number	Name and Address of the manufacturer	Information website for patients
LOT Lot Number / Batch Code	UDI Unique Device Identifier	MD Device Name
MR MRI Conditional		

United Orthopedic Corporation
No. 16, Luke 1st Rd. Luzhu Dist.,
Kaohsiung City 82151, Taiwan.
For additional information, please visit:
https://www.unitedorthopedic.com

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