INSTRUCTIONS FOR USE
SIMPLICITI™ SHOULDER SYSTEM

IFU-7224 Rev. A

IMPORTANT

The implantation of a joint prosthesis requires knowledge of anatomy, biomechanics, and reconstructive surgery of the musculoskeletal system and may be performed only by a qualified surgeon. The surgeon must operate in accordance with current information on the state of scientific progress and the art of surgery. Patients should be aware of the possible complications that can occur as a result of disregarding the precautions listed below.

CAUTION

The Federal (United States) Law restricts this device to sale, distribution and use by or on the order of a physician.

DESCRIPTION

The Tornier Simpliciti™ Shoulder System is intended for use in Total Shoulder Arthroplasty of the shoulder application. As a Total shoulder, the system consists of a metaphyseal metal humeral component, a metal humeral head and an ultrahigh molecular weight polyethylene glenoid.

For a more detailed description of the implants and their utilization, please refer to technical documentation, or contact your Tornier representative. It is essential to implant the SIMPLICITI™ Shoulder System with the SIMPLICITI™ instrumentation specifically designed for this purpose. The SIMPLICITI™ Shoulder System implants are not compatible with components from other manufacturers. Glenoid components are labeled "for cemented use only" and are indicated only for use with bone cement. The metaphyseal humeral components are indicated and labeled for press-fit un-cemented use.

MATERIALS

The materials used in the manufacture of the SIMPLICITI™ Shoulder System implants are as follows:

-Metaphyseal humeral component is made of titanium alloy (Ti-6AL-4V) in accordance to ASTM standard F136 with a sintered titanium (CP Ti) bead coating conforming to ASTM F-1580.

-The humeral heads are made off cobalt-chromium- alloy (CoCr) according to ASTM standard F1537.

-The glenoid components are made of ultrahigh molecular weight polyethylene (UHMWPE) according to ASTM standard F648 or ISO 5834-2.

INDICATIONS FOR USE

Intended Use:

The Simpliciti™ Shoulder System is intended for Total Shoulder Arthroplasty of the shoulder.

Indications for Use:

The Simpliciti Shoulder System is indicated for severely painful and/or disabled joint resulting from osteoarthritis or traumatic arthritis.

The metaphyseal humeral components are indicated for press-fit, un-cemented use; Glenoid components are labeled for cemented use only and are indicated only for use with bone cement. This device is for Single Use.

CONTRAINDICATIONS

The SIMPLICITI™ Shoulder System is contraindicated in the following situations:

1. Lack of sufficient sound bone to seat and support the implant, including that resulting from skeletal immaturity, osteoporosis or erosive arthritis
2. Metal allergies or sensitivity
3. Infection at or near the site of implantation
4. Distant or systemic infection

POSSIBLE ADVERSE EFFECTS

A time course distribution of the adverse events reported in the clinical investigation of the Simpliciti System is provided in Table 1.

Table 1: Time-Course Distribution of Adverse Events reported in the clinical trial for the Simpliciti System

Adverse Events	**Frequency**						**Percent of Population (N=157)[1]**
Visit	Immediate Post-Op	2 wk	3 mo	6 mo	12 mo	24 mo	
System Related							
Aseptic Glenoid Loosening	0	0	0	0	0	**1**	0.6%
Procedure Related							
Arthrofibrosis, treated shoulder	1	0	0	0	0	0	0.6%
Ecchymosis	0	1	0	0	0	0	0.6%
Hematoma	0	1	0	0	0	0	0.6%
Infection	1	0	**1**	0	0	0	1.3%
Keloid Scar	0	0	1	0	0	0	0.6%
Mental Status Changes	0	1	0	0	0	0	0.6%
Osteoarthritis	0	0	0	0	0	1	0.6%

Adverse Events	Frequency						Percent of Population (N=157)[1]
Pain	0	0	0	0	0	1	0.6%
Parasthesias	2	0	2	1	0	0	3.2%
Residual Parasthesia	0	1	0	0	0	0	0.6%
Scarring	0	0	1	0	0	0	0.6%
Shoulder Stiffness treated arm	0	0	2	0	0	0	1.3%
Tendonitis	0	0	1	0	0	0	0.6%
Weakness	0	0	0	1	**1**	0	1.3%

[1]All percentages for adverse events are based on the number of occurrences reported in a patient population of 157 subjects.
Boldface numbers represent revision/explant due to the given adverse event.

Study investigators classified relatedness of all AEs as definitely related, possibly related, unknown relatedness, or not related to the study system or procedure. There were 22 (22/228, 9.6%) AEs in 21 subjects (21/157, 13.4%) that were considered related to the system or procedure. One (0.4%) AE was considered possibly related to the system. Ten (4.4%) events were reported as definitely related to the procedure and 11 (4.8%) were reported as possibly related to the procedure. All system or procedure related events were considered expected complications for total shoulder arthroplasty; thus, there were no Unanticipated Adverse Device Effects (UADEs).

There were 55 reported serious AEs (SAEs). Three (3/55, 5.5%) SAEs were possibly (2) or definitely (1) related to the procedure and one (1/55, 1.8%) SAE was possibly related to the system.

CLINICAL STUDIES

A prospective multi-site clinical investigation of the Simpliciti System involving 157 (Table 2) subjects conducted in the United States to determine safety and effectiveness of the device. Subject outcomes were compared to a performance goal established from results of a historical control group with a primary diagnosis of arthritis and implanted with a FDA cleared, Tornier stemmed humeral prosthesis. All clinical results and adverse events for this investigator were derived from the Simpliciti System that had a single humeral nucleus, universal (left and right) design humeral head, and a universal design glenoid component.

Table 2: Patient Demographics for the Simpliciti IDE Study

Characteristic	% (n/N) or Mean ± SD (range)
Sex:	
Male	71.3% (112 / 157)
Female	28.7% (45 / 157)
Age (years)	65.5 ± 8.6 (37-84)
Shoulder Diagnosis:	
Glenohumeral Arthritis: GH Arthritis with Massive RCT/CTA	0.6% (1 / 157)
Glenohumeral Arthritis: Primary OA	95.5% (150 / 157)
Glenohumeral Arthritis: Instability OA / Capsulorrhaphy Arthropathy	1.9% (3 / 157)
Post Traumatic Arthritis: Chondral Injury	1.3% (2 / 157)
Post Traumatic Arthritis: Malunion Proximal Humerus Fracture	0.6% (1 / 157)
Shoulder treated:	
Right	54.8% (86 / 157)
Left	45.2% (71 / 157)
Body Mass Index (kg/m)	30.7 ± 5.4 (17.8 - 47.8)

Table 3: Device Accounting for the Simpliciti IDE study based on number of completed clinical follow-up examinations

	Pre-Op	2wk	3mo	6mo	12mo	24mo
Theoretically Due	157	157	157	157	157	157
Deaths (cumulative)	0	0	0	0	1	1
Explant (cumulative)	0	1	1	1	1	2
[1] Simpliciti Revision (cumulative)	1	1	2	2	2	3
[2] Expected	157	156	156	156	155	154
[3] Clinical Follow-Up	157	156	156	156	154	149

	Pre-Op	2wk	3mo	6mo	12mo	24mo
[4] %Follow-up	100%	100%	100%	100%	99.35%	96.8%

[1] Subjects were continued to be followed since they still had components of the originally implanted system.
[2] Theoretically Due – (Deaths + Explant)
[3] Cases with complete clinical data
[4] Clinical Follow-Up/Expected

Each subject was evaluated pre-operatively, 2 week, 3, 6, 12, and 24 month post-operative intervals. All operative and post-operative complications, device related or not, were recorded for subjects enrolled in the investigation. All device and procedure related adverse events are listed in Table 1.

Clinical results were evaluated using the Constant-Murley Score (CS) and radiographic data. Constant Scores were completed at each follow-up except at 2 weeks. Radiographs were only collected at 2 weeks, 12 and 24 months. Independent radiologists reviewed radiographs. See Table for clinical study results.

A subject was a Patient Success at 24-months if:

- There was NO continuous radiolucent line around the prosthesis; and
- The adjusted Constant Score was > 85; and
- They did not have revision surgery; and
- They did not have a system-related serious adverse event.

Table 4: Simpliciti IDE Clinical Study Results

	Pre-Op	24 month
Total Subject Visits	157	151
[1] Cases with complete CS	153	149
Average CS	55.6	103.8
Cases with CS > 85		91.3% (136/149)
Continuous radiolucent line around prosthesis at 24 months		0
[2] Revisions/Explants		5
[3] System Related SAE		1
[4] Successful Cases		134
Percent Success		88.74% (134 / 151)

[1] Two subjects did not have strength test completed at 24 months
[2] Number of components removed or revised at 24 months
[3] Aseptic Glenoid Loosening
[4] A successful case required a CS > 85, no revision/explant of any component, no continuous radiolucent line around the nucleus, and no system related SAEs
[5] Denominator includes cases with complete and incomplete CS, radiographic data, SAEs, and revisions/explants

There were five subjects with revisions (3) and explants (2) of the Simpliciti system. The three revisions were for nucleus upsize during initial implant (1), infection 4 weeks post-implant (1), and aseptic glenoid loosening 17 months post-implant (1). The two explants were for poor bone quality during the initial implant and Subscapularis insufficiency 467 days post-implant.

SAFE COMBINATION
The Simpliciti Nucleus (metaphyseal humeral components) has been designed to be compatible with both the Simpliciti and Simpliciti Soft Tissue Balancing humeral head systems. Additionally, both humeral head systems, in certain combinations, are compatible with the Tornier Aequalis and Affiniti glenoid systems. For more information on the cleared combinations refer to the mismatch charts in Tornier document CAW-3185.

WARNINGS AND PRECAUTIONS
This product is provided sterile in an undamaged package and is for ONE TIME USE ONLY. If either the implant or the package appears damaged, expiration date has been exceeded or if the sterility is questioned for any reason, the implant should not be used. DO NOT clean, re-sterilize or reuse as this may damage or compromise performance of the devices and may expose patient to risk of transmitting infectious diseases.

- Do not re-use this device.
- Do not use with devices from other manufacturers.
- Do not use trials as implants.
- Do not alter or modify the implant.

MRI WARNING:
This product has not been evaluated for safety and compatibility or tested for heating or migration in the MR environment.

Patients should be informed that there are several different manufacturers and generations of MRI equipment, and Tornier Inc. cannot make claims regarding the compatibility of this product with any specific MRI unit. It is recommended that patients and physicians consult with the MRI equipment manufacturers to discuss the compatibility of this product with the MRI equipment before undergoing any MRI procedure.

CAUTIONS
The functional life expectancy of this device has not been determined.

If the surgeon determines this implant is appropriate for a patient with any of the following conditions, the surgeon must advise the patient of the strength limitations of the implant, the possibility of implant dislocation, migration, loosening or failure and the precautions the patient must take to minimize the possibility of an adverse clinical result.

These conditions may impose severe loading on the device:
1. Obesity
2. Engaging in manual labor or activities
3. Certain sports activities
4. Patient youth and activity level
5. Medical conditions or balance impairments that could lead to falls
6. Alcohol or drug addiction
7. Mental attitudes or disorders that could result in failure to follow surgeon orders

These conditions may adversely affect the fixation of shoulder implants, if the conditions create a poor environment or poor bone stock:

1. Marked osteoporosis, tumors or generally poor bone stock
2. Metabolic or systemic disorders, pharmacological treatments
3. History of general or local infections
4. Severe deformities
5. Allergic reactions to implant materials
6. Tissue reactions to implant corrosion or wear debris
7. Disabilities of other joints

SURGICAL PROCESS

- **Pre-operatively:**

The surgeon must be fully conversant with all the aspects of the surgical technique and know the indications and contra-indications of this type of implant. The surgeon must have acquainted himself before the operation with the specific operative technique of the product which is available from the manufacturer. As part of the pre-operative examination, the surgeon must check that no biological, biomechanical or other factors are present that will affect the correct conduct of the operation and the postoperative period. An appropriate range of sizes must be available at the time of the operation. Check that the implant package has not suffered from any deterioration.

- **Per-operatively:**

The correct selection of the type and size of the implant appropriate to the patient and the position of the implant are extremely important. Handle the implant using proper aseptic technique including the use of sterile surgical gloves. Leave the protective cover on until the device is needed. The functional surfaces of the implant must not suffer any damage, abrasion or other deterioration. Do not increase the anteversion of the glenoid component as it may result in instability and dislocation. Before closing the incision, clean out all ectopic bone, extraneous cement and bone chips as debris left in the site may cause dislocation, pain, restricted movement or pre-mature wear.

- **Post-operatively:**

Patients should be informed about the precautions they must take in everyday life to help maximize the service life of the implant. It is recommended that a regular postoperative follow-up be undertaken to detect early signs of wear, loosening of the prosthesis, etc., and to consider the action to be taken. Normal wear of the implant according to the state of knowledge at the time of its design cannot in any way be considered to constitute a dysfunction or deterioration in the characteristics of the implant. A suitable rehabilitation program must be designed and implemented.

STORAGE AND HANDLING

The Simpliciti™ Shoulder System implants must be stored in their original sealed packaging. Implants must be handled with care to preserve the integrity of the packaging.

PACKAGING AND STERILIZATION

The implants are individually packaged and supplied Sterile. All metal implants have been sterilized by gamma irradiation. All polyethylene implants have been sterilized using gamma with an inert gas packaging. The expiration date for sterilization must be checked. Only those products implanted before the end of the expiration date may be considered sterile. The packaging and labeling must be checked for integrity. Reject any implant if the packaging is damaged. Every precaution must be taken to ensure sterility when opening the packaging of the implant and when inserting it. Never re-sterilize and implant.

RETRIEVAL AND ANALYSIS

Retrieval and Analysis of Simpliciti Shoulder System should be performed in accordance with the Simpliciti Protocol.

LIMITED WARRANTY

Tornier, Inc. warrants that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse or improper handling of the product subsequent to receipt by the purchaser. Tornier, Inc. does not warrant the outcome of the surgical procedure.

SYMBOLS KEY

Symbol	Meaning
REF	Catalog Number
SN	Serial Number
	Caution
	Consult Instructions for Use
	Do Not Reuse
	Do Not Re-Sterilize
	Not Made with Natural Rubber Latex
	Do Not Use if package is damaged
STERILE R	Sterilized using Irradiation
Rx Only	Caution: Federal Law (USA) restricts this device to sale by or order of a physician
	Use By Date
	Manufacturer

T Marking on Implant denotes the Material is Titanium
C Marking on Implant denotes the Material is Cobalt Chrome

Manufacturer:
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