WRIGHT™

FOCUSED EXCELLENCE

HANDLING OF WRIGHT MEDICAL DISPOSABLE PROPHECY™ ANKLE INSTRUMENTS

153290-0

The following languages are included in this packet:

English (en)

For additional languages, visit our website www.wright.com

Then click on the **Prescribing Information** button.

For additional information and translations please contact the manufacturer or local distributor.

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℞ ONLY

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Attention Operating Surgeon

IMPORTANT MEDICAL INFORMATION

HANDLING OF WRIGHT MEDICAL DISPOSABLE PROPHECY™ ANKLE INSTRUMENTS (153290-0)

DEFINITIONS

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Definition
LOT	Batch code
REF	Catalog number
2	Do not re-use
!	Caution, consult accompanying documents
i	Consult operating instructions
	Use by
	Temperature limitation
	Keep dry
	Keep away from sunlight
	Date of manufacture
	Manufacturer
EC REP	Authorized EC Representative in the European Community
STERILE EO	Sterilized using ethylene oxide
STERILE R	Sterilized using radiation
STERILE GAS	Sterilized using gas plasma
℞ ONLY	For prescription use only
MR	MR Conditional
	Do not use if packaging is ripped or damaged.
Abbreviation	Material
Ti	Titanium
Ti6Al4V	Titanium Alloy

CoCr	Cobalt Chrome Alloy
Al2O3	Alumina
ZrO2	Zirconia
SS	Stainless Steel
UHMWPE	Ultra High Molecular Weight Polyethylene
CaSO4	Calcium Sulfate
HA	Hydroxyapatite
PMMA	Polymethylmethacrylate

GENERAL PRODUCT INFORMATION

These surgical instruments are designed for single use only. They are manufactured with certain patient-specific features which render them unusable in cases other than that for which they were designed. These surgical instruments are supplied clean and non-sterile, and must be sterilized before use. After use, these instruments must be properly disposed of. The following information outlines the proper steps for processing Wright Medical disposable surgical instruments.

A. INTENDED USE

Wright's PROPHECY Preoperative Navigation Alignment System is intended to be used as patient specific surgical instrumentation to assist in the positioning of total ankle replacement components intraoperatively and in guiding the marking of bone before cutting. The PROPHECY Preoperative Navigation Alignment Guides are intended for use with Wright's INBONE, INFINITY and INVISION Total Ankle Systems and their cleared indications for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans. The PROPHECY Preoperative Navigation Alignment Guides are intended for single use only. The PROPHECY Preoperative Reports are intended for use with Wright's INBONE, INFINITY and INVISION Total Ankle Systems and their cleared indications for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

B. PRECAUTIONS

PROPHECY Guides and bone models are patient-specific, single use, and disposable. Never re-use the guides and models.

The PROPHECY Pre-operative Navigation System should only be used by trained and qualified surgeons.

Markings on guides and models provide case identifiers, such as case number, and must be legible. Before using the guides and models, check the identifier and confirm that it corresponds with the current case. Do not use the guide or the model if the case identifiers are not legible.

Do not use the surface-matched guides if stable contact is not achieved between the guide and the underlying patient's anatomy. Loss of contact between the guide and the underlying anatomy may result in improper pin position.

Care should be taken when drilling the pins to ensure that placement pins do not cause internal soft tissue damage.

Do not alter the guides and the models from their original shape. Debris from the alteration could contaminate the operating region. In addition, altering the size of the guide may lead to an improper fit on the patient's anatomy.

Do not implant.

If the device is unable to be used for any reason, the surgeon should be prepared to use traditional instrumentation to perform the procedure.

C. ADVERSE EFFECTS

The following are adverse effects, which should be understood by the surgeon and explained to the patient prior to surgery:

a. Peripheral neuropathies have been reported following total joint surgery. Subclinical nerve damage has been reported, and may occur as the result of surgical trauma resulting in pain or numbness of the affected limb;
b. Cardiovascular disorders including venous thrombosis, pulmonary embolism, or myocardial infarction;
c. Damage to blood vessels;
d. Dislocation and subluxation of prosthetic components can result from improper positioning and/or migration of the components. Muscle and fibrous tissue laxity can also contribute to these conditions;
e. Infection can lead to failure of the joint replacement. On rare occasions, arthrodesis of the involved joint or amputation of the limb may be required;
f. Bone damage or fracture may occur during installation due to compromised bone quality, osteoporosis, or previous bone injury or surgery;
g. Allergic reactions to the component materials can occur;
h. Hematoma;
i. Delayed wound healing;
j. Pain;
k. Bone fracture by trauma or excessive loading, particularly in the presence of poor bone stock;
l. Periarticular calcification or ossification, with or without impediment to joint mobility; and
m. Inadequate range of motion due to improper selection or positioning of components or periarticular calcification.

D. LIMITATIONS AND RESTRICTIONS OF REPROCESSING

The medical provider must match the case number provided on design paperwork with the case number on the device labeling. End of functional life is intended to be the conclusion of the case for which the device was designed. These instruments are created based on patient-specific data which may be subject to change at varying rates depending on the patient condition. It is up to the medical provider to determine if the patient's condition or anatomy may have changed sufficiently to require redesign of the device. Extreme care should be taken not to drop or contaminate the device during surgery. All unused devices must be destroyed upon the conclusion of the case for which the devices were designed.

E. PACKAGING

Wright Medical packaging is intended to protect instrumentation during shipping. Health care personnel bear the ultimate responsibility for ensuring that any packaging method or material, including a reusable rigid container system, is validated for use in sterilization processing and sterility maintenance in a

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particular health care facility. Testing should be conducted in the health care facility to assure that conditions essential to sterilization can be achieved. Wright Medical is not responsible or liable for the sterility of the instrumentation supplied by Wright Medical.

F. STERILIZATION

Wright Medical instruments manufactured from Nylon may be steam sterilized with no detrimental effects. All items to be sterilized must be packaged appropriately for the type of sterilization. The package must permit contact of the sterilant with the item, while also serving as a barrier to microorganisms, during any storage period. Users should wear non-linting gloves, i.e. Latex or Nitrile, when handling instruments, to minimize bioburden and particulates.

G. WARNINGS

- When handling instruments use extreme caution to avoid injury: consult with an infection control practitioner to develop and verify safety procedures appropriate for all levels of direct instrument contact.

STEAM STERILIZATION

The minimum recommended steam sterilization conditions for Wright instruments are as follows:

1. Double wrap the component in an FDA-cleared CSR wrap or a similar type non-woven medical grade wrapping material.
2. Autoclave according to the following parameters:

Steam Sterilization		
Prevacuum 270˚F (132˚C)	Preconditioning Pulses	3
	Exposure Temperature	270˚F (132˚C)
	Exposure Time	4 minutes
	Dry Time	20 minutes

3. After sterilization, remove the component from its wrapping using accepted sterile technique with powder-free gloves. Ensure that the component is at room temperature prior to use. Avoid contact with hard objects that may cause damage.

These recommendations are consistent with ANSI/AAMI ST79 have been developed and validated using specific equipment Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your environment. If processing conditions, wrapping materials, or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.

H. STORAGE

Surgical instruments that will not be utilized within a short time should be stored clean, and completely dry. The packaging that items are in may offer an effective barrier to prevent contamination of the item. The type of packaging required for steam sterilization is an FDA-cleared CSR wrap or non-woven medical grade wrapping material. This packaging type offers a level of protection from contamination, which must be consistent with the final intent of the item. The surgical instruments must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.

CAUTION: U.S. Federal Law restricts this device to sale or use by or on the order of a physician.