HANDLING OF WRIGHT DISPOSABLE PROPHECY® ANKLE INSTRUMENTS
150870-0

The following languages are included in this packet:

English (en)

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

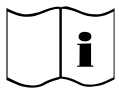
(150870-0)

OUTLINE:

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
	Batch code
	Catalog number
	Do not re-use
	Caution, consult accompanying documents
	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
STERILE A	Sterilized using aseptic processing techniques
℞ ONLY	For prescription use only
	Do not use if packaging is ripped or damaged

Abbreviation	**Material**
Ti	Titanium
Ti6Al4V	Titanium Alloy
CoCr	Cobalt Chrome Alloy
SS	Stainless Steel
UHMWPE	Ultra High Molecular Weight Polyethylene

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 Guides are 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® and INFINITY™ 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.

B. 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.

C. 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 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.

D. 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.

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	16 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 ST79:2010 and A1:2010, Table 5, Row 1 and 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.

E. 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.

F. REFERENCES

ISO 17664:2004(E) Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices

AAMI TIR 12:2004 Designing, testing and labeling reusable medical devices for reprocessing in healthcare facilities: A guide for device manufacturers

ANSI/AAMI/ISO17665-1:2006, Sterilization of health care products - Moist heat - Part 1 Requirements for the development, validation and routine control of a sterilization process for medical devices.