Experience predictability

CADENCE is designed for predictable procedures with

- Streamlined instrumentation
- Advanced anatomic design

Smith+Nephew

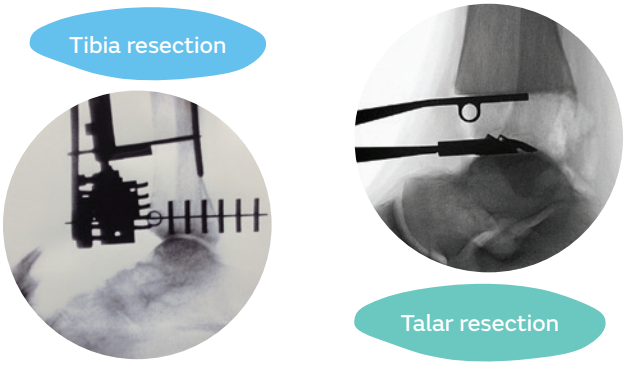
CADENCE◊
Total Ankle System

CADENCE◊ is designed for predictable procedures

Designed for efficiency in the OR through:

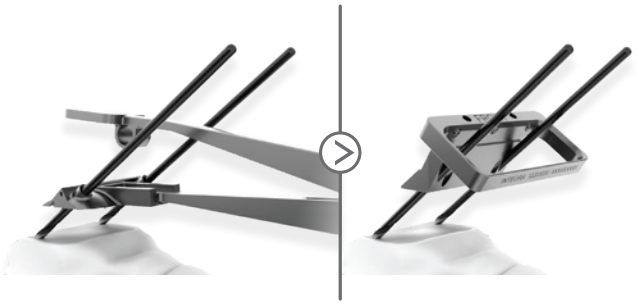
Reproducible implant alignment

due to instruments with fluoroscopic cues



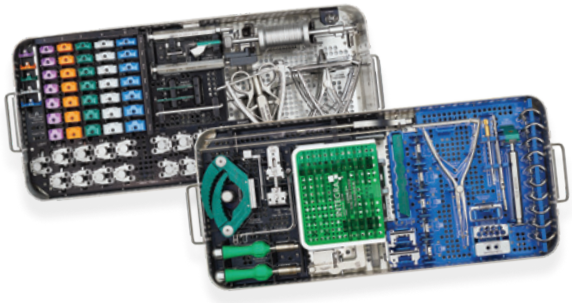
Repeatable talar preparation

with pins that set the location of multiple guides



Intuitive tray and instrument layout

to facilitate procedure flow



Faster mean OR time[1]

as compared to reported OR times[2,3] of Wright Medical Infinity® and InBone® with Prophecy® PSI

Designed for optimal fit through:

Anatomic tibial baseplate

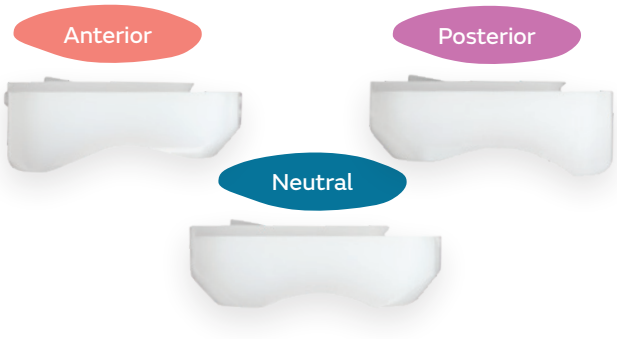
with fibular sulcus

Anatomic talar implant

with conical axis of rotation available in chamfer and flat cut designs

Biased poly options

to address sagittal deformities



Customizable implant combinations

to treat a variety of patient anatomies*

>1,000
Implants combinations

*Number of available implant combinations varies by country and region

Indications

The CADENCE◊ Total Ankle System is designed to treat ankle arthritis through replacement of the ankle joint with a prosthesis, thereby reducing pain, restoring alignment, and allowing for movement at the replaced joint.

The CADENCE Total Ankle System is indicated for use to treat:

- Systemic arthritis of the ankle (e.g. rheumatoid arthritis, hemochromatosis)
- Primary arthritis (e.g. degenerative disease)
- Secondary arthritis (e.g. post-traumatic, avascular necrosis, if minimally 2/3 of the talus is preserved)

CADENCE Total Ankle System is also indicated for revision surgeries following failed total ankle replacement and non-union/mal-union of ankle arthrodesis, provided sufficient bone stock is present.

Note: In the United States, this device is intended for cemented use only.
Note: Outside the United States, this device is intended for cemented or cementless use.

Contraindications

The CADENCE Total Ankle System is contraindicated for:

- Active infection
- Skeletally immature
- Pregnancy
- Suspected or documented metal allergy or intolerance
- Severe avascular necrosis of the talus/tibia
- Severe malalignment or instability that is not surgically correctable
- Neurological or musculoskeletal disease that may adversely affect gait or weight bearing
- Participation in activities that may exert excessive loading on joint area and prosthesis
- Inadequate neuromuscular status (e.g. prior paralysis, neuropathy)
- Poor bone stock, poor skin coverage, or excessive bone loss around the joint which would make the procedure unjustifiable
- Obesity
- Steroid use

The following conditions present an increased risk of failure:

- Severe osteoporosis; marked bone loss or revision procedures for which an adequate fit of the prosthesis cannot be achieved
- Osteomalacia
- Metabolic disorders
- Demonstrates physiological or anatomical anomalies
- Undergoing immunosuppressive therapy
- Malignancy/local bone tumors
- Compromised wound healing
- History of mental illness/instability and non-compliance
- History of drug abuse and/or addiction

Warning: This device is not intended for subtalar joint fusion or subtalar joint impingement. Please carefully evaluate the anatomy of each patient before implantation.

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References

1. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). 2000 Feb 29. Identifier NCT03142958, A Post-Market, Prospective, Non-Randomized, Multi-Center, Open-Label, Clinical Evaluation of the Integra® CADENCE◊ Total Ankle System in Primary Ankle Joint Replacement; 2017 May 8. Available from: https://clinicaltrials.gov/ct2/show/ NCT03142958?term=CADENCE&draw=2&rank=3. **2.** Hamid KS, Matson AP, Nwachukwu BU, Scott DJ, Mather RC, DeOrio JK. Determining the cost-savings threshold and alignment accuracy of patient-specific instrumentation in total ankle replacements. Foot & Ankle International. 2017;38(1):49-57. **3.** Savage-Elliott I, Wu VJ, Wu I, Heffernan JT, Rodriguez R. Comparison of time and cost savings using different cost methodologies for patient-specific instrumentation vs standard referencing in total ankle arthroplasty. Foot & Ankle Orthopaedics. 2019;4(4).

Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

- Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.
- Warning: Applicable laws restrict these products to sale by or on the order of a physician.
- Consult product labels and inserts for any indications, contraindications, hazards, warnings, precautions, and instructions for use.

Additional information for EMEA Customers only:
Products mentioned in this document are CE class I, IIa and IIb devices. Contact Integra should you need any additional information on devices classification. All the medical devices mentioned on this document are CE marked according to European council directive 93/42/EEC on medical devices and its relatives, unless specifically identified as “NOT CE MARKED”.