Instructions for Use

Salto Talaris® Total Ankle Prosthesis

Rx ONLY
Federal (USA) law restricts this device to sale by or on the order of a physician.

Important
The manufacturer recommends that all personnel responsible for handling and implanting the devices read and understand this information before use. The implantation of a joint prosthesis and its associated implants 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. Surgical training is required as a prerequisite to implant the Salto Talaris® Total Ankle Prosthesis. The patient must be properly informed about the device and the information contained in the present instructions for use.
Description
The Salto Talaris Total Ankle Prosthesis is a semi-constrained prosthesis consisting of two mating components: a metal tibial tray in association with an insert and one of two metal talar dome options; a chamfer-cut resurfacing talar dome implant or a flat-cut talar dome implant.

X-ray templates are provided to select the size of the implant prior to the surgery. Ancillary instruments are also provided:
• Trial pieces for testing implantation during the surgery.
• Instruments for the assembly and proper implanting of the prosthesis.

For a more detailed description of the implants and their utilization, please refer to the technical documentation or contact your Integra representative. It is essential to implant the Salto Talaris Total Ankle Prosthesis with the Integra® instrumentation specifically designed for this purpose. Integra implants must be assembled using Integra components defined as being compatible with one another. The selection of the appropriate implants can be made by using the recommendations of the surgical technique and the trial pieces and x-ray templates supplied with the instrumentation.

Symbols can be used to identify some implants (labeling or marking).

They have the following meaning:

L = left; R = right;

TH = thickness.

Recommendations about how to associate components with each other are mentioned in the following drawing. For a standard tibial cut, the cut is performed at 8mm. To prevent any risk of medial malleolus fracture, the tibial cut cannot exceed +2mm above the current cut.
Figure 1. Compatibility of components for Integra Salto Talaris Total Ankle Prosthesis System

*Note – Only one talar dome component should be selected.
Material
The constituent material of the Salto Talaris implants is labeled on the packaging. The tibial tray and the talar dome implants are manufactured from cobalt chromium alloy (CoCr) according to ISO standard 5832-4. The insert is manufactured from implant grade ultra high molecular weight polyethylene (UHMWPE) according to ISO standard 5834-2. Tibial and talar implants are coated with plasma-spray porous titanium according to ASTM 1580.

Note – per ISO 5832-4, the allowable limits of Cobalt (Co), Chromium (Cr), Nickel (Ni) and Molybdenum (Mo) are as follows: Co - 61.5% max; Cr - 26.5-30%; Ni - 1% max; Mo - 4.5-7.0% max.

MRI
The Salto Talaris Total Ankle Prosthesis has not been evaluated for safety and compatibility in the MR environment. The Salto Talaris Total Ankle Prosthesis has not been tested for heating or migration in the MR environment. There is no proven incompatibility of the prosthesis to the MR environment. However, as a precaution, it is recommended not to expose a patient wearing the prosthesis to the MR environment.

Intended Use
The Salto Talaris Total Ankle Prosthesis is intended for replacement of the ankle joint to reduce pain and restore ankle function compared with preoperative status.

Indications for Use
The Salto Talaris Total Ankle Prosthesis is indicated as a total ankle replacement in primary or revision surgery for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.

Components are intended for cemented use only in the USA.
Contraindications
Known contraindications to date:

- Sepsis.
- Infection sequelae.
- Systemic infection, fever and/or local inflammation.
- Complete talar necrosis.
- Insufficient quantity of bone stock or poor skin coverage around the ankle joint that would make the procedure unjustifiable.
- Persisting skin lesion.
- Important ligament laxity.
- Severe osteoporosis.
- Ankle arthrodesis with malleolar exeresis.
- Neuromuscular or mental disorders which might jeopardize fixation and postoperative care.
- Neurobiologic diseases.
- Nonfunctional lower limb muscles.
- Complete loss of ankle collateral ligament.
- Charcot’s arthropathy.
- Elevation of WBC count.
- Distant foci of infection from genitourinary, pulmonary, skin and other sites; dental focus infection which may cause hematogenous spread to the implant site.
- Bone immaturity.
- Known allergy to one of the materials.
- Patient pregnancy.
Warnings and Precautions

• Never re-use an implant, even if it seems to be in perfect condition, to prevent any risks of cross-contamination or a risk of reduced performances.
• Never re-sterilize an implant delivered sterile.
• Never modify an implant.

The following conditions tend to adversely affect ankle replacement implants:
• Obesity or excessive patient weight.
• Manual labor.
• Active sports participation and/or high activity level.
• Likelihood of falls.
• Alcohol and/or drug addiction.
• Other disabilities, as appropriate.
• Poor bone stock.
• Metabolic disorders or systemic pharmacological treatments leading to progressive deterioration of solid bone support for the implant (e.g. diabetes, steroid usage, immunosuppressive treatments).
• Compromise of the ligaments or other supporting soft tissue structures such that they cannot withstand expected loads following arthroplasty, due to, for example, rheumatoid arthritis or other diseases affecting the quality of the soft tissue.
• Severe deformities of the joint.
• Tumors of the supporting bone structures.
• Sensitivity, allergy or other reactions to implant materials.
• Elevation of sedimentation rate unexplained by rheumatoid arthritis may adversely affect ankle replacement implants.
• Inability of the patient to follow the surgeon’s recommendations and the physical therapy program.
Adverse Effects
The following are the most frequent adverse events after ankle arthroplasty:

- Dislocation
- Infection
- Poor wound healing
- Loosening of components
- Instability
- Bone fracture
- Secondary necrosis of the talus
- Neuropathies
- Disassembly or breakage of components
- Possible metal sensitivity

Preoperative Care
The surgeon must be fully conversant with all aspects of the surgical technique and know the indications and contraindications for 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 Integra representative. As part of the preoperative examination, the surgeon must check that no biological, biomechanical or other factors may affect the correct conduct of the operation and the postoperative period. He must also check that the quality of the bone is satisfactory enough to support the implantation. An appropriate range of sizes must be available at the time of the surgery.

Intraoperative Care
The correct selection of the type and size of the implant appropriate to the patient and the positioning of the implant are extremely important. Never use an insert of a larger size than the size of the tibial tray. Check the proper anterior/posterior positioning of the tibial tray implant before impaction and that the insert lateralization is respected according to the side operated on.
The use of trial pieces allows for the proper size selection of the implants. Frequent radioscopic checks allow the position of the prosthesis to be checked.

The prostheses must not be used if their functional surfaces have been damaged or have undergone shock, abrasion, or other deterioration. In case of revision, special care must be taken not to damage the components that are not removed.

**Postoperative Care**

The surgeon must inform patients:
- About precautions to take in daily life to guarantee maximum implant survival.
- About the fact that their weight and level of activity can affect the life span of the prosthesis.
- That it is contraindicated to use physiotherapy devices transmitting electrical or acoustic energy (ultrasounds, etc.) near the implant.
- That they must inform the surgeon of any change in performance (mobility, pain, etc.)

It is recommended that a regular postoperative follow-up is undertaken to detect early signs of wear, loosening of the prosthesis, etc., and to consider an appropriate course of action. Normal wear of the implant in respect of the state of knowledge at the time of its design cannot in any way be considered to constitute a malfunction or a deterioration in the characteristics of the implant. A suitable rehabilitation program must be designed and implemented specific to the patient.

**Sterility**

The implants are supplied sterile (gamma radiation). The expiration date for sterilization and integrity of the packaging must be checked.

An implant whose packaging is open or damaged or whose expiration date has passed must not be used.
Every precaution must be taken to ensure sterility when opening the packaging of the implant and during implantation.

**Do not re-sterilize this product.**

Ancillary instruments may be supplied sterile.

For handling and sterilization of non-sterile ancillary instruments, refer to the instrument reprocessing instructions for use. The X-ray templates are supplied non-sterile and should not be sterilized prior to use.

For any other information regarding the ancillary instruments, refer to the instructions provided for this purpose.

**Storage**
Implants must be stored in their original sealed packaging. Implants must be stored away from heat or moisture. Implants must not be exposed to direct sunlight, ionizing radiation or particulate contamination. Implants must be handled with care to preserve integrity of the packaging.

**Implant Retrieval and Handling**
In case of retrieval of the implant from the patient, the retrieved implant should be handled according to appropriate and validated hospital procedures.

**Surgical Procedure**
A Surgical Technique brochure is available which outlines the basic procedure for device implantation and use of the specialized surgical instrumentation. It is the responsibility of the surgeon to be familiar with the procedure before use of these products. Each surgeon must evaluate the appropriateness of the surgical technique used based on personal medical training and experience.
Meticulous preparation of the implant site and selection of the proper size implant increase the potential for successful reconstruction. A complete set of instruments for each type of implant is available to aid bone preparation and reduce the operative time. It is suggested that the proper size implant be removed from its sterile package only after the implant site has been prepared and properly sized.

**Training**
Surgeon training is required by a qualified instructor prior to implanting the Salto Talaris Total Ankle Prosthesis to ensure thorough understanding of the implantation techniques and the instrumentation.

**Product Information Disclosure**
INTEGRA HAS EXERCISED REASONABLE CARE IN THE SELECTION OF MATERIALS AND THE MANUFACTURE OF THESE PRODUCTS. INTEGRA EXCLUDES ALL WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. INTEGRA SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. INTEGRA NEITHER ASSUMES NOR AUTHORIZES ANY PERSON TO ASSUME FOR IT ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THIS PRODUCT.
## Symbols Used on Labeling

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>🏰</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>📌</td>
<td>Lot number</td>
</tr>
<tr>
<td>📚</td>
<td>Catalog number</td>
</tr>
<tr>
<td>⌛️</td>
<td>Use-by date (YYYY-MM-DD)</td>
</tr>
<tr>
<td>📚</td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td>🚫</td>
<td>Do not use if package is damaged</td>
</tr>
<tr>
<td>✖️</td>
<td>Do not re-use</td>
</tr>
<tr>
<td>🎨</td>
<td>Do not re-sterilize</td>
</tr>
</tbody>
</table>

- **STERILE** R: Sterilized using irradiation
- **Cemented**: Cemented use
- **MATL: CoCr**: Cobalt chromium alloy
- **MATL: Ti6Al4V**: Titanium alloy
- **MATL: UHMWPE**: Ultra high molecular weight polyethylene
- **Rx ONLY**: Federal (USA) law restricts this device to sale by or on the order of a physician.