INSTRUCTIONS FOR USE

POLYETHYLENE INSERT FOR TORNIER SALTO ANKLE PROSTHESES:
SALTO, SALTO TALARIS, SALTO TALARIS INTERNATIONAL & SALTO XT

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 musculo-skeletal 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 ankle prostheses. The patient must be properly informed about the device and the information contained in the present instructions for use.

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

1. Description:
The polyethylene insert of the Tornier Salto ankle prosthesis is an ultra high molecular weight polyethylene (UHMWPE) insert associated to a Tornier Salto metal tibial plate and a Tornier Salto metal talar resurfacing component.

Inserts of the Tornier Salto ankle prosthesis are available in two models:
- fixed insert right & left:
  the polyethylene insert is fixed to the tibial plate and articulates with the talar implant.
  - Sizes 00 & 0: thicknesses 8, 9, 10 & 11mm
  - Sizes 1 to 3: thicknesses 8, 9, 10, 11, 13, 15, 17, 19 & 21mm
- mobile insert right & left*:
  the polyethylene insert between the tibial plate and the talar implant is free and articulates within these two components.
  - Size 0: thicknesses 4, 5, 6, 7 & 8 mm
  - Sizes 1 to 3: thicknesses 4, 5, 6, 7, 8, 9, 10, 11 & 13 mm

The fixed inserts must be attached to the tibial plates of the Tornier Salto ankle prostheses: Salto (fixed version), Salto Talaris, Salto Talaris International & Salto XT (except for 00 size).

Special remark for the revision of the Salto or Salto Talaris size 0 implant:
There is no size 0 for the Tornier Salto XT ankle prosthesis. During revision of a Salto or Salto Talaris size 0 prosthesis, certain implant compatibility rules need to be respected. Only the tibial implant may be revised using a Salto XT size 1 if the patient’s anatomical conditions allow it. In this case, a size 0 implant, compatible with a Salto XT size 1 tibial implant and a talar size 0 implant should be used. The mobile inserts* are only used with the mobile tibial components of the Tornier Salto (mobile version*) ankle prosthesis.

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 Tornier representative. It is essential to implant the Tornier Salto polyethylene insert with the Tornier instrumentation specifically designed for this purpose. Tornier implants must be assembled using Tornier components defined as being compatible with one another. Only tibial and talar components of the Tornier Salto ankle prostheses are compatible with polyethylene inserts of the Tornier Salto ankle prosthesis. The selection of the appropriate implants can be made by using the recommendations of the surgical technique and the trial pieces and 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.

All the models are not cleared in all countries, please contact your local distributor for information about the availability.

Use of Tornier ankle prostheses without bone cement is not cleared in the USA.

2. Materials:
The constituent material of the Tornier inserts is labeled on the packaging. The polyethylene insert is manufactured from implant grade ultra high molecular weight polyethylene (UHMWPE) according to ISO standard 5834-2.
The radiolucent wire present in the mobile* polyethylene inserts is in chromium cobalt alloy (CoCr) according to ISO standard 5832-7.

3. Intended use:
The Salto ankle prostheses are intended for replacement of the ankle joint to reduce pain and restore ankle function compared with preoperative status.

4. Indications for use:
Tornier polyethylene inserts have the same indications as the tibial and talar implants of the associated Salto ankle prosthesis. Please refer to the indications given in the instructions for use supplied with the associated implants.

5. 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.
6. Side-effects and possible complications:
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.

7. Warnings and cautions:
- 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 the 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.

• Pre-operatively:
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 Tornier 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.

• Intra-operatively:
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 plate. Check the proper anterior/posterior positioning of the tibial 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.

• Post-operatively:
The surgeon must inform patients about:
- precautions to take in daily life to guarantee maximum implant survival,
- the fact that their weight and level of activity can affect the life span of the prosthesis.

It is contraindicated to use physiotherapy devices transmitting electrical or acoustic energy (ultrasounds…) near the implant. The inserts of Salto Tornier ankle prostheses have not been evaluated for safety and compatibility in the MR environment. The inserts of Salto Tornier ankle prostheses have not been tested for heating or migration in the MR environment.
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.

8. Storage and handling:
Implants must be stored in their original sealed packaging. The storage place must be away from humidity. Implants must not be exposed to direct sunlight, ionising radiation, extreme temperatures nor particular contamination. Implants must be handled with care to preserve integrity of the packaging.

9. Packaging and sterilization:
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. Ancillary instruments may be supplied sterile. For handling and sterilization of non-sterile ancillary instruments, refer to the ancillary instruments instructions. The templates are supplied non-sterile and should not be sterilized.
For any other information regarding the ancillary instruments, refer to the instructions provided for this purpose.

*The mobile inserts and the tibial mobile components of the Salto ankle prosthesis are not available for sale within the United States.
Interpretation of terms and symbols

- Do not use if package is damaged
- Do not resterilise
- Non-sterile
- Consult instructions for use
- Caution, consult accompanying documents
- Catalogue number
- Serial number
- Batch code
- Sterilized using irradiation
- Do not reuse
- Use by

Manufacturer:
TORNIER SAS
161, rue Lavoisier
38330 MONTBONNOT SAINT MARTIN - FRANCE
Tél: +33 (0)4.76.61.35.00 – Fax: +33 (0)4.76.61.35.33

USA Business address:
TORNIER INC
10750 Cash Road
Stafford, TX 77477
(888) 867-6437

The French text is the reference text.

Code GMDN:
48180 : ankle prosthesis bearing

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