Alpha Ankle Arthroplasty
Surgical Technique

Triple A
Alpha Ankle Arthroplasty

Surgical Technique
CONTENTS

Introduction and references 5
Design rationale 5
Indications & contra-indications 6
Pre-operative planning 6
Component features 7
Surgical technique
  Preparation and opening 8
  Assembly of the alignment instrument 9
  Alignment & referencing 10
  Tibial resection 11
  Tibial preparation for the component stem 14
  Talar and bearing sizing 15
  Talar resection 16
  Trial reduction 17
  Insertion of the components 18
Post-operative regime 19
Components 19
Instrumentation 20

Copyright Information: AAA® is a registered trademark of  Alphamed Medizintechnik Fischer GmbH. The use and copying of the contents of this brochure, even partially, is only allowed with the prior approval of the Alphamed Medical Fischer GmbH
The AAA® Ankle Arthroplasty Ankle system was developed in collaboration with:

Univ.Prof. Dr. Michael FELLINGER, Graz
Univ.Doz. Dr. Ernst ORTHNER, Wels
and Prim. Dr. Robert SIORPAES, St. Johann i.T.

The licensee of the worldwide patent is Alphamed Medizintechnik Fischer Lassnitzhöhe, Austria

The AAA® Team
Alphanorm Medizintechnik GmbH
Schwarzl Medical Center
Hauptstrasse 140
A-8301 Lassnitzhöhe
Tel.: +43 3133 2527
Fax: +43 3133 2527 - 13
E-mail: info@alphamed-fischer.at
Internet: www.alphaanklearthroplasty.com

All implants and instruments of the AAA® ankle replacement system are manufactured under CE regulations by implantcast GmbH in Buxtehude, Germany

Disclaimer: This surgical technique is intended exclusively for physicians. Information on the components, instrumentation and procedures is of a general nature and does not represent medical advice or recommendations. Each patient must be examined and advised individually, and this document does not replace the need for such examination or advice.
INTRODUCTION:

For a long time tibiotalar arthrodesis was the preferred method of treatment of patients with a degenerative, inflammatory or post-traumatic disease of the ankle. (1,2,3)

Ankle fusions are not without their limitations. The advantages of ankle arthrodeses are limited to pain reduction, stable fixation, improvement in stable ambulation and reduction of deformity. Activities such as running and jumping, where active plantar flexion and/or dorsiflexion are required, may be limited.

Potential short-term problems are the risk of pseudarthrosis, which has been described in 4% to 36% of cases, non-union and infection. In the long term there is a risk of disturbed gait, significant deterioration in the ipsilateral joints and functional impairment following arthrodesis in post-traumatic, rheumatic and primary osteoarthritis. (4-5-6)

Ankle arthroplasty has certain theoretical advantages over ankle arthrodesis, both in mono-articular and certainly in poly-articular disease: the gait pattern is less affected and adverse effects on the other joints of the lower extremities are rarely to be expected. (7)

High failure rates of the two component ankle implants has prevented ankle arthroplasty from becoming recognised as an acceptable alternative to arthrodesis. The intrinsic limitation of such implants lead to unacceptably high shear and tensile forces on the bone-prosthesis interface, which may in turn lead to mechanical failure. (8,9,10)

The introduction of the second generation of implants began in the 1980s with the modern Total Ankle Replacements such as the Buechel-Pappas in the U.S.A. and the Scandinavian Total Ankle Replacement in Europe. At this moment almost all Total Ankle Replacements are of the semi-constrained type, requiring cementless placement with minimal bone resection and utilising components adapted for bone ingrowth. Metal-backed tibial parts, polyethylene bearing inserts and large contact areas are other mutual design characteristics.

THE TRIPLE-A DESIGN

It was our goal to design Total Ankle components and instrumentation with the following criteria:

- Extended range of indications. To date, many designs limit the patient selection to those without major deformities, without ligamentous instability and with good range of motion. Clinically this means that in most orthopaedic practices about 90% of patients with an end-stage of degenerative, rheumatoid or post-traumatic disease of the ankle would receive an arthrodesis.

- Increase the stability of the replaced joint in extension, without limiting the free anatomical movements or plantar and dorsiflexion. A more stable design does not seem to affect the clinical results. (12)

- Referencing the bone cuts and stabilizing the soft tissues not only from the tibia only but from the fully extended leg, extends the application of Total Ankle Replacement to patients with more pronounced bone deformations.

- Changing the method and reducing the level of the talar preparation to retain surgical options and increase clinical results of future revision surgery or arthrodesis.

LITERATURE:

(7) Doets HC, Nelissen RGHH, ET AL. Gait analysis after total ankle arthroplasty: Presented as a podium presentation at the AAOS 2005 Feb 23-27; Washington, DC.
WHAT IS NEW WITH THE TRIPLE-A PROSTHESIS

- New patented guiding geometry of the sliding movements at that side of the joint where the least movement occurs, thereby limiting polyethylene wear.
- The design of the components is such that most of the movements do not take place between tibial component and bearing but between the polyethylene bearing and the talar component, possibly reducing the chance of cyst formation in the tibial region.
- Changing the preparation for the talar bone from cutting to a precise, reproducible and predictable milling technique. Milling of the talus is millimeter precise and carried out under direct vision thereby limiting the removal of bone to the minimum.
- The metal components are coated with titanium nitride resulting in extremely durable surfaces and reduced wear. The titanium nitride coating also has an allergy preventing effect, so that this implant may be used in metal sensitive patients.
- To encourage bone ingrowth the bone interface of the prosthesis has a titanium plasma spray porous coating (approximately 250μ pore size), covered with the Bonit®1 Biphasic CalciumPhosphate coating.
- The special shape of the bearing increases the stability of the prosthesis, allowing for implantation under physiological ligamentous tension, thus increasing the range of motion.
- When designing any prosthesis, the remaining surgical option for future revision surgery should be considered. Minimal bone resection allows for a broader range of revision options and increases outcome results in cases where an arthrodesis is indicated.
- Combining the unique design and a simplified and standardized surgical technique surgeons have been able to successfully revise prostheses of other types with a Triple-A prosthesis.

INDICATIONS for the implantation of a Total Ankle Replacement is arthrosis of the tibiotalar joint which cannot be treated with conservative and/or other joint preserving methods. Prerequisites for the successful implantation of a total ankle replacement is sufficiently stable bone stock and an infection-free joint.

CONTRAINDICATIONS: manifest infections, bone necrosis of the talus, which exceed one-third of the talus, or have reached a level that stable anchoring of the talar component is impossible, and neuropathic arthropathies such as Charcot’s foot. No evidence of periferal arterial disease. If suspected then PAD should be excluded by angiography.

PRE-OPERATIVE PLANNING
The preoperative planning is based upon standard X-rays of the ankle: The AP X-ray is made in the lateral plane and with 20° of internal rotation. Additionally for the clinical and radiological assessment of the leg axis a full leg x-ray is recommended. An assessment of the neighbouring joints (talotarsalis, subtalar joint) must be performed as well as an evaluation of the vitality and bone quality of the talus.

In the case of bone loss or (suspected) cystic changes, a Computer Tomography Scan or MRI is recommended.

X-ray templates are provided for pre-operative planning. Digital templating is available for mediCAD® and Orthoview®. Please contact your local representative for information.

For more detailed information on indications and contra indications we refer the reader to the Instructions for Use which are supplied with each of the components of the Triple-A ankle system.
AAA® COMPONENTS DESIGN FEATURES
- Surgical alignment utilising the full leg length axis
- Minimal resection using precise, spherical milling of the talus
- Full stability in extension through congruency between tibia component and bearing
- Unrestricted rotation between tibia and bearing
- Dorsiflexion and plantar flexion between bearing and talar component with increased lateral stability

THE AAA® RANGE OF MOTION
- Dorsiflexion: 135 degrees
- Plantarflexion: 20 degrees
- Unrestricted axial rotation

THE AAA® TIBIAL COMPONENTS
- Longitudinal oval depression provides for semi-constrained rotation between tibial component and the bearing
- Stem provides maximal bone contact and rotational stability, necessary for secondary fixation: bone ingrowth
- A conical shaped stem compensates for postoperative subsidence and eases revision
- 5 sizes

THE AAA® POLYETHYLENE BEARINGS
- Reduced risk of dislocation through semi-constrained design
- Semi-constrained AP-movements
- Semi-constrained rotational movements
- Highly congruent to the articulating surfaces of the metal counter parts
- 4 sizes, each with 4 heights: 6, 8, 10 and 12 mm

THE AAA® TALAR COMPONENTS
- Anatomical design
- High initial stability through optimal press-fit
- Spherical contact to the milled talar bone
- The round, central peg allows for correct rotational seating of the component, the second peg provides rotational stability and together they provide optimal contact and stability for bone ingrowth.
- Minimal bone resection (resurfacing)
- 4 Sizes
POSITIONING

Unless contraindicated and assuming that there is sufficient mobility of the other joints in both lower extremities, the patient is positioned supine on the operating table. The patient’s leg is placed in a leg holder, in such a way that the knee can be flexed and the lower leg can be placed in a neutral position.

STANDARD PREPARATION

A surgical glove is an additional barrier can be used to prevent bacterial or fungal infection originating from the foot. The procedure is started with the tourniquet turned “off”. The tourniquet is switched “on” when bleeding prevents a good view of the ankle, usually following the arthrotomy. For better wound healing, the tourniquet time should be set to a maximum of 80 minutes.

ACCESS step 1:

A longitudinal incision is centered over the ankle immediately lateral to the anterior tibial tendon. The incision is deepened to the ankle joint while retracting the neurovascular bundle and extensor hallucis longus laterally.

ACCESS step 2:

The superficial branch of the peroneal nerve in the foot is identified and is retracted carefully to the lateral aspect of the ankle.

ACCESS step 3:

The ankle capsular tissue is incised, elevated and mobilised exposing the medial and lateral malleoli.
STEP 1A:
The distal aspect of the tibia alignment guide is placed approximately 5 millimetres proximal to the tibial plateau and aligned over the tibial crest.

STEP 1B:
The telescoping rod allows for exact positioning of the cutting block over the ankle joint. The femoral alignment guide is placed in the alignment tower and positioned centrally over the femoral head.

STEP 1C:
The image intensifier is used to check the correct placement over the femoral head.

STEP 2:
Cutting blocks are available: one block for tibia size 1 and 2, one for size 3 and 4 and one for size 5. Two types of tibial cutting block holders are available with either a neutral or the standard 5 degree slope. An estimate of the size of the tibial cutting block to be used is made and this cutting block is attached to the cutting block holder. The final selection of the cutting block of the appropriate size and its attachment to the cutting block holder is made in step 8.

STEP 3:
The tibial alignment guide, with the cutting block holder and the provisional cutting block in place is fixed to the bone with the plastic strap.
**STEP 4:**
The alignment tower is reattached to the tibial fixation block and proper alignment is checked with fluoroscopy of the femoral head, the centre of the knee and the ankle, pointing towards the second toe.

**STEP 5:**
Once the correct placement is confirmed the alignment tower is removed and the tibial alignment block is fixed to the tibia by pre-drilling and placement of a central pin. The guide rod can still be adjusted here by sliding it over the fixation block for the correction of a slight valgus or varus in the knee.

**STEP 6:**
The alignment guide should be positioned parallel to the longitudinal axis of the tibia. Adjustments can be made both on the tibial head side as on the ankle side.

**STEP 7:**
The distal tibial cutting block is positioned in the right ML position and fixed with the knurled knob. Length can be equally adjusted and the cutting block holder can be rotated axially. The 5° cutting block is preferred in primary cases, for revision cases the 0° will reduce the amount of bone to be resected.
STEP 8:
Cutting blocks are available in 3 sizes (L/R on either side of the block): one block for tibia size 1 and 2, one block for size 3 and 4 and one for size 5.

STEP 9:
Two 150 mm pins are placed on the inside of both the malleoli. Alignment is checked with the alignment rod, pointing at the second toe and passing in the centre between the two pins. At this point also correct alignment over the femoral head should be re-checked. The two pins are used later also to check the correct position of the foot.

STEP 10:
The alignment guide is fixed to the tibial crest using a predrilled 2.5 mm, 100 mm long pins and tightened with the knurled knob.

STEP 11:
The knurled knobs have an internal hexagonal slot to allow for extra tight fixation, using the standard hex head screw driver provided.
**STEP 12:**
Using a trephine drill (Ø 2.5 mm) drill through the two proximal medial and lateral holes. (The oval holes should not be used for drilling!)
Two 100-mm pins are inserted into these proximal holes to protect the malleoli from the saw blade when making the horizontal cut.

**STEP 13:**
Drilling the other distal holes bicortically prepares the vertical cuts.

**STEP 14:**
The distal tibia is then resected through the slot in the distal tibial cutting block using an oscillating saw.

**STEP 15A:**
The distal tibial cutting block is removed and using the distal face of the distal cutting block holder as guide the tibial cut is finished.
STEP 15B:
The distal tibial cutting block is removed. The 4 laterally made drill holes are interconnected using a reciprocating saw, being careful no to fracture the medial malleolus.

STEP 16:
After carefully removing the resected distal tibial bone the correct size of the tibial component is determined using the tibial sizer.

STEP 17:
The tibial alignment guide can now be removed. The pins are retained, in case later repositioning is required. The tibial stem guide of the selected size is placed flush with the resected distal tibia, it is then centred and fixed with two short pins (prepare using a trephine drill Ø 2.5 mm.)

STEP 18:
Using the three recessions in the proximal stem guide to direct the drill, three parallel holes are drilled and interconnected with a 6 mm chisel. This is to prepare for the cookiecutter to be used in the next step.
STEP 19:
Using the same instrument as a proximal stem guide an 4.5 cm long oscillating saw is used to prepare the recession for the stem of the implant.

STEP 20:
The cookie cutter is used to finalise the preparation for the stem of the tibial implant. The removed bone block is preserved to be put back in place at the end of the procedure.

STEP 21:
Note that the junctions between the tray and the stem of the tibial trial are formed a rasp. Carefully insert this instrument into and removed from the prepared bone until the tray is completely seated.

STEP 22:
A trial instrument is used to check the bone preparation.
STEP 23:
Starting with size 6 mm, a trial talar implant is inserted between the prepared tibial bone and the talar to determine the correct size of the talar component to be used. The trial implant should be able to be inserted into the gap without force, avoiding tensing the soft tissues, but the onlay should not be able float freely within the joint. Check at this stage the alignment and stability of the ankle. If the ankle is not stable medially, a release of the deltoid ligament or an osteotomy of the medial malleolus should be performed. A correction of the lateral tendon should be considered at this stage, but should not be performed before the final components have been inserted.

STEP 24:
The correct selection of the size is confirmed using this measuring device. Make sure that there is no overhang in the ML-direction.
In general, conform the AAA® design a talar component will be selected smaller than or equal in size to the tibial component.

STEP 25:
Assembly of the drill guide for the fixation of the talar stem. The spacer sizing instrument is chosen, a drill guide of the appropriate size is selected and the spacers are attached. The spacer is inserted to check the size and the tension. Should the lateral and medial tension be equal but the talus is oblique, then a higher or lower trial spacer should be tried, until the required tension and stability is achieved.
The appropriate setting of the drill guide is determined using the table (a sterilisable table is provided in the instrument tray).
In this example using a size 1 Talar component combined with a 10 mm bearing will require the talar drill guide to be set to 5.
STEP 26:
The foot is placed in 30 degree plantar flexion, with the calcaneus aligned with the full leg axis. A 2.5 mm. drill is inserted into the talar using the drill guide. Upon completion of the pre-drilling the 150 mm pin can be inserted. In the lateral x-ray the pin should be positioned vertical to the talar surface and the tip should end at the processus lateralis tali.

STEP 27:
The footplate of the drill guide should lie flush with the resected bone of the distal tibia.

STEP 28:
The handle of the drilling guide is removed. The 8mm canulated drill is guided by the pin and a hole is drilled till the depth marked on the drill is reached. For the slight correction of the position of the pin a special correction drill guide is provided.

STEP 29:
Starting with the 11 mm, a guide dowel is inserted into the prepared hole. This guide dowel will serve as a guide for the talar reamer.
STEP 30:
The talar reamer of the appropriate size is advanced over the guide dowel until the subchondral plate is reached. In the case of a hard boney plate it is recommended to ream in two steps with the prereamer provided. The goal is to ream as little of the subchondral bone as possible.

STEP 31:
The guide dowel is removed and any overhanging bone is removed using an osteotome.

STEP 32:
The trial talar component is placed first, followed by the trial tibial component.

STEP 33:
With the two trial components in place the trial bearing is inserted and the joint is checked for stability and range of motion.
STEP 34:
The talar component is positioned with the larger peg first, allowing fine tuning of the position of the components. With the talar component in the correct position the position is marked through the small hole at the front of the trial implant. A drill is used to make an additional hole for the engagement of the second fixation pin of the final component, providing adequate rotational stability.

STEP 35:
For the final placement, the talar component is inserted first and gently tapped into place, using the talar impactor.

STEP 36:
The tibial component is inserted with the component impactor and gently seated.

STEP 37:
A final trial reduction is performed with a trial bearing to check that the selected height provides the desired stability and range of motion. The final polyethylene bearing is inserted and the window of the tibial stem is closed with the previously preserved bone block.
AAA® POSTOPERATIVE PROTOCOL

Note:
Individual patient factors and additional procedures at surgery should be considered when developing a postoperative protocol. A suggested protocol is provided below:

- If the wound condition is clean and dry, typically 2 to 4 days after surgery, the foot is placed in a stabilizing cast or walker protecting the ankle from eversion, inversion, and plantar flexion movements for 6 weeks.
- Weight bearing is allowed as tolerated after 3 weeks.
- A rehabilitation program should be started for the foot and ankle after cast or walker removal.
- First clinical and radiological control is made at 6 weeks, to check wound status, osteointegration and position of the implants.

AAA® COMPONENTS

<table>
<thead>
<tr>
<th>Size 1</th>
<th>Size 2</th>
<th>Size 3</th>
<th>Size 4</th>
<th>Size 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tibia component</td>
<td>Talar component</td>
<td>PE bearing 6 mm</td>
<td>PE bearing 8 mm</td>
<td>PE bearing 10 mm</td>
</tr>
<tr>
<td>Size 1</td>
<td>0022-0011</td>
<td>0022-001</td>
<td>0022-106</td>
<td>0022-108</td>
</tr>
<tr>
<td>Size 2</td>
<td>0022-0012</td>
<td>0022-002</td>
<td>0022-206</td>
<td>0022-208</td>
</tr>
<tr>
<td>Size 3</td>
<td>0022-0013</td>
<td>0022-003</td>
<td>0022-306</td>
<td>0022-308</td>
</tr>
<tr>
<td>Size 4</td>
<td>0022-0014</td>
<td>0022-004</td>
<td>0022-406</td>
<td>0022-408</td>
</tr>
<tr>
<td>Size 5</td>
<td>0022-0015</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
AAA® Tibial Alignment Guide
REF 0022-0102

AAA® Replacement band for Tibial Alignment Guide
REF 0022-0102-10

AAA® Tibial Alignment Tower
REF 4223-0004

AAA® Tibial Resection checker
REF 4223-0009

AAA® Telescopic Alignment Rod 6 x 400 mm
REF 4223-0035

AAA® Hex head screwdriver short
REF 0280-1007

AAA® Cutting block
REF 0022-1063  5 degrees
REF 0022-1064  0 degrees
Alpha Ankle Arthroplasty

AAA® INSTRUMENTATION TRAY 1

AAA® Tibial Cutting Block
REF 0022-0101    Size 1
REF 0022-0103    Size 3
REF 0022-0105    Size 5

Fixation Pins
REF 7700-0110  2.5 / 50 mm (6x)
REF 7700-0111  2.5 / 100 mm (6x)
REF 7700-0119  2.5 / 150 mm (6x)

AAA® Pin Inserter 2.5 mm
REF 7700-0108

AAA® Drill 2.5 x 110 mm with AO quick fix
REF 0022-1062

AAA® Drill 2.5 x 180 mm with AO quick fix
REF 0022-1180

AAA® Pin Extractor
REF 7512-0800

AAA® Tibial Template modular
REF 0022-1171  Size 1
REF 0022-1172  Size 2
REF 0022-1173  Size 3
REF 0022-1174  Size 4
REF 0022-1175  Size 5

AAA® Quick Fix Handle, inverted
REF 0022-1006

AAA® Guide for Tibial Window
REF 0022-1181  Gr. 1
REF 0022-1182  Gr. 2
REF 0022-1183  Gr. 3
REF 0022-1184  Gr. 4
REF 0022-1185  Gr. 5

AAA® Quick Fix Handle, modular
REF 0022-1012

AAA® Chisel for Tibial Window
REF 0022-0133

AAA® Tibial Rasp
REF 0022-0116

AAA® Quick Release Chuck
REF 4223-0022
AAA® Talar Guide
REF 0022-1212 Size 1 / 2
REF 0022-1234 Size 3 / 4

AAA® PE Trial Inlay
REF 0022-3106 Size 1/6 mm
REF 0022-3108 Size 1/8 mm
REF 0022-3110 Size 1/10 mm
REF 0022-3112 Size 1/12 mm
REF 0022-3206 Size 2/6 mm
REF 0022-3208 Size 2/8 mm
REF 0022-3210 Size 2/10 mm
REF 0022-3212 Size 2/12 mm
REF 0022-3306 Size 3/6 mm
REF 0022-3308 Size 3/8 mm
REF 0022-3310 Size 3/10 mm
REF 0022-3312 Size 3/12 mm
REF 0022-3406 Size 4/6 mm
REF 0022-3408 Size 4/8 mm
REF 0022-3410 Size 4/10 mm
REF 0022-3412 Size 4/12 mm

AAA® Drill handle
REF 0022-1037

AAA® Spacer Plate
REF 0022-1010

AAA® Spacer
REF 0022-1106 6 mm (2x)
REF 0022-1108 8 mm (2x)
REF 0022-1110 10 mm (2x)
REF 0022-1112 12 mm (2x)

AAA® Drill Guide modified
REF 0022-1049

AAA® Correction Guide Straight
REF 0022-1065

AAA® Talar Drill modular
REF 0022-1040
AAA® INSTRUMENTATION TRAY 2

AAA® Stamp
REF 0022-1130 8 mm
REF 0022-1131 9 mm
REF 0022-1132 10 mm
REF 0022-1133 11 mm

AAA® Impactor
REF 7210-0001

AAA® Starter Reamer
REF 0022-1047 I modular
REF 0022-1048 II modular

AAA® Talar Reamer modular
REF 0022-1071 Size 1
REF 0022-1072 Size 2
REF 0022-1073 Size 3
REF 0022-1074 Size 4

AAA® Talar Trial Implant modular
REF 0022-1161 Size 1
REF 0022-1162 Size 2
REF 0022-1163 Size 3
REF 0022-1164 Size 4

AAA® Talar Impactor
REF 0022-0141

AAA® Tibial Impactor
REF 0022-0100

AAA® Tibial Trial Implant modular
REF 0022-1151 Size 1
REF 0022-1152 Size 2
REF 0022-1153 Size 3
REF 0022-1154 Size 4
REF 0022-1155 Size 5

AAA® Alignment Scale for Drill Guide
REF 0022-1070
All implants and instruments of the AAA® ankle replacement system are manufactured under CE Regulations by implantcast GmbH in Buxtehude, Germany.