Integra™

Hintegra® Total Ankle Prosthesis
Primary Surgery

SURGICAL TECHNIQUE
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1. Description

- The HINTEGRA® Total Ankle Prosthesis is a three-component design that:
  - resurfaces the tibia and talus by minimal bone resection,
  - incorporates a mobile inlay.
- The anatomical shape of the unique design of the HINTEGRA® Total Ankle Prosthesis provides:
  - high intrinsic stability,
  - low contact stresses to the bone,
  - low ligament stress,
  - minimal wear.
- The double coated surface (porous titanium + HAP) allows:
  - uncemented fixation,
  - short time for bone ingrowth (osteointegration).
2. Technical features

PE Inlay

- Ultra high density polyethylene.
- High congruency with the metal surfaces of both tibial and talar components.
- Unconstrained rotatory gliding (sagittal and frontal plane) on flat tibial surface.
- Free sagittal plane motion on conically shaped talar surface.
- Large contact area with both tibial and talar components to provide:
  - low contact stresses.
  - minimal wear.
  - intrinsic stability against eversion-inversion forces.
- X-rays markers (Titanium alloy TA6V).
- PE inlay sizes:

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- Both Hintegra® Sensitive tibial and talar components must be used with the PE inlay labeled "Hintegra® sensitive compatible".
- The PE inlay labeled "Hintegra® sensitive compatible" is intended to be used with Hintegra® prosthesis and Hintegra® Sensitive prosthesis. It is made out of UHMW Polyethylene, with X-rays markers made out of Titanium Alloy.
**Talar component**

- Anatomical shape (conical surface):
  - to allow physiological talar motion.
  - to minimize medial ligament stress.
- Minimal bone resection required.
- Double coating (Porous Titanium and HAP) for optimal bone ingrowth (osteointegration).
- Anterior pegs to improve sagittal stability and positioning.
- Medial and lateral rims to guide movement of the PE inlay.
- Anterior shield to prevent ingrowth of osteophytes.
- Two holes in the shield for optional additional screw fixation.
- Talar component sizes:

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**Optional tibial cortical screws**

- Tibial cortical screws dia. 4.0 mm are available if an additional stability is required on tibial component.
- Length is adapted to the size of the tibia.
3. Material

Introduction

The regular version of the HINTEGRA® prosthesis is composed of metallic parts:

- Tibia and talus are made of Cobalt Chromium alloy (containing up to 1% Nickel).
- Optional tibial screws are made of Stainless Steel (containing 9 to 11% Nickel).

Especially adapted to the biomechanical stresses in the joint and for optimal wear resistance.

Hintegra® Sensitive prosthesis has been designed to reduce the exposure to metallic ions present in the Chrome Cobalt alloy substrate.

The sensitive version of the HINTEGRA® prosthesis is still composed of metallic parts:

- Tibia and talus are made of Cobalt Chromium alloy (containing up to 1% Nickel) coated with TiN (Titanium Nitride) layer.
- Optional tibial screws are made of Titanium alloy (Nickel free).

This golden cover limits allergenic ions release.

Less risks of allergic reactions (reduced Nickel exposure).

Materials

<table>
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<tr>
<th>Talar &amp; tibial components</th>
<th>PE inlay</th>
<th>Optional tibial cortical screws</th>
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<tr>
<td>S</td>
<td>• Cobalt Chromium alloy (CoCr) ISO 5832-4, with Double coating (Porous Ti + HAP).</td>
<td>• Titanium alloy (TA6V) ISO 5832-3 &amp; ASTM F136 Sensitive compatible</td>
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<td></td>
<td>• Titanium Nitride (TiN) coating</td>
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Surgical technique • Hintegra® PRODUCTS FOR SALE IN EUROPE, MIDDLE-EAST and AFRICA ONLY
Indications

- Systemic arthritis of the ankle (e.g. rheumatoid arthritis).
- Primary osteoarthrosis (e.g. degenerative disease).
- Secondary osteoarthrosis (e.g. post-traumatic, infection, avascular necrosis*).
- Failed total ankle replacement.**
- Salvage for non-union and malunion of ankle joint fusion.**

* if minimally 2/3 of the talar body is preserved.
** if bone stock is sufficient.

The patient’s joint must be anatomically and structurally limited to receive the selected implant.

Contraindications

Relative contraindications

- Severe osteoporosis.
- Immunosuppressive therapy.
- The size 0 of both Hintegra® intermediary sliding core and talar components must not be implanted in a patient weighing more than 65 kilogrammes.
- High demanding sport activities (e.g. contact sports, jumping).

Absolute contraindications

- Recent infection.
- Avascular necrosis of the talus/tibia > 1/2.
- Severe misalignment.*
- Severe instability.*
- Diabetic syndrome.
- Suspected or documented metal allergy or intolerance.

* if not surgically correctable.

The Titanium Nitride (TiN) coating of the Hintegra® Sentitive Total Ankle Prosthesis allows to minimize the risk of allergies to Chrome Cobalt alloy.

The size 0 of both Hintegra® intermediary sliding core and talar components must not be implanted in a patient weighing more than 65 kilograms.
Surgical Technique

Developed with the cooperation of Pr. Beat Hintermann, Liestal - Switzerland.

NEWDEAL as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

1. Positioning of the patient

- The patient is positioned with the feet on the edge of the table.
- The affected foot is maintained on a block to facilitate treatment of associated problems (e.g. subtalar arthrodesis, ligament reconstruction, tendon transfer).
- The ipsilateral back is lifted until a strictly upward position of the foot is obtained.

2. Surgical approach

- An anterior longitudinal incision of 10 to 12cm length is made to expose the retinaculum.
- The retinaculum is dissected along the lateral border of the anterior tibial tendon, and the anterior aspect of the distal tibia is exposed.
- While the soft tissue mantel is dissected with the neurovascular bundle that runs behind the long extensor hallucis tendon.
- Arthrotomy is made, and hooks are inserted to carefully keep the soft tissue mantle away. A self-retaining distractor may be helpful; attention must be paid, however, that no tension is applied to the skin.
- Osteophytes on tibia are removed, particularly on antero-lateral aspect.
- Osteophytes on talar neck and anterior aspect of medial malleolus are also removed.
- The fibula can usually not be fully visualized at this stage.
3. Positioning of the tibial cutting block

**Preparation**

- The tibial cutting block (309 753 + 309 773), the tibial rod (309 615), the tibial positioning V (309 625), alignment rod connector (309 620), and translation block (309 630) are assembled on the table before positioning on the patient. The distal cutting block (309 773) is fixed in an intermediate position to allow vertical adjustment later on.
- The proximal end of the tibial device (Tibial positioning V 309 625) is adjusted to the tibial tuberosity while its arms are held open and then closed.

**Attention has to be paid not to expose the fibular head to compression (risk of nerve injury).**

- Proximal neutral position of the tibial rod is obtained while the translation block (309 630) is positioned on the middle of the sliding part of the tibial positioning V (309 625).
- The distal tibial cutting block (309 773) is positioned on the center of the distal tibial metaphysis and fixed by 2 pins.

**Settings**

For proper positioning, the following adjustments have to be made:

**Sagittal plane**

The rod must be positioned parallel with the anterior border of the tibia.

**Frontal (coronal) plane**

The tibial rod must be placed in the center of the tibia: proximally, it is projected onto the tibial tuberosity, and distally, it is projected onto the center of the distal tibia.
**Vertical adjustment**

- The distal tibial cutting block (309 773) is moved proximally until the desired resection height is achieved. Usually, a resection of approximately 2 mm to 3 mm upper from the apex of the tibial plafond is desired.
- Tighten the knurl 2 with the screwdriver (309 645).

**NOTE**

In varus ankles, thicker tibial resection is usually needed. Whereas, in valgus ankles, and/or in presence of high joint laxity, less bone resection is advised.
Rotational setting

- If necessary, the distal tibial cutting block (309 773) is rotated to get a parallel position of its medial surface to the medial surface of the talus; this might prevent hitting the medial malleolus with the sawblade during resection.
- Tighten the knurl 3 with the screwdriver (119 645).

4. Tibial resection

Positioning of the tibial cutting guide

- The tibial cutting guide is selected, depending on the size of the tibia. 3 different cutting guides (SMALL - 309 637, MEDIUM/STANDARD - 309 636 and LARGE - 309 635) are available; small and large are optional. Usually, the standard one (MEDIUM - 309 636) is used in order to protect the lateral and the medial malleoli. The largest one (LARGE - 309 635) should be used only for very large ankles but in that case, a special attention must be paid to the malleoli using the sawblade.
- The guide is slid into the cutting block creating a slot in which the sawblade will be guided. The width of the slot limits the excursion of the sawblade, thereby protecting the malleoli from hitting and fracturing.

Attention should be paid to the proper contact of the tibial cutting block with the anterior surface of the tibia.
First cut

- The tibial resection is performed with the adequate saw blade, inserted into the slot of the tibial cutting block.

Make sure that the saw blade is perfectly in an antero-posterior position in order to avoid any damage to the malleoli.

Opening of the joint

- The tibial cutting guide is removed, and the Hintermann® distractor (119 664) is mounted with provided K-wire 2.5 mm (115 225) to the antero-medial aspect of the distal tibia and the antero-medial talar neck, respectively.

K-wires should be placed in such a position that they do not hinder further preparation of the talus.

- Obtained distraction allows to get better insight into the tibiotalar joint, and to facilitate the removal of the posterior resected parts. K-wires can be cut to limit their bulkiness.
Finalisation

- Once the tibial cut is made, a reciprocating saw may be used to finalize the cuts, particularly for the vertical cut on medial side.

Attention should be paid not to insert the saw blade too deeply into the joint as the tibial nerve might be at risk. Because the bone of the distal tibia is particularly hard postero-medially, an osteotome should be used only with caution: its use can easily break the malleolus.

- The distal part of the tibia being resected, emphasis should be given to achieve a properly edge-shaped cut (90°) along the medial malleolus. This will allow, later on, to insert the tibial component properly along the medial malleolus.

- In most instances, there is still some bone left on lateral side of the tibia. The horizontal cut is carefully completed with the oscillating saw until the fibula becomes completely visible.

- The resected bone is removed using a rongeur. Some bone and capsular tissue on posterior aspect of the joint might be left in place at this stage of surgery (it is more easily removed once the talar cuts are performed), as long as it may not hinder insertion of the talar cutting block.

5. Positioning of the talar cutting block

Insertion of the block

- The talar cutting block (309 656 or 309 657) is inserted into the tibial cutting block (309 773) until it has been fixed by the snapping mechanism.

- The proximal tibial knurl (2) is unlocked and the distal tibial cutting block is moved as distally as possible until the collateral ligaments are tightened; now the knurl is locked.

Fixation of the block

- While the foot is held in neutral position, 2 pins, 70 mm long (309 605), are inserted medially and laterally.

- Alignment of the hindfoot and flexion position of the foot are checked visually. If proper foot position is not achieved, the pins must be removed and the procedure should be done again.
6. Talar cuts

6-1 Superior cut

- The resection of the talar dome is done with the oscillating saw using a Newdeal® saw blade. The cut is done through the slot of the talar cutting block (309 656).

NOTE if necessary, appropriate positioning of talar cut can be checked (e.g. contact of the talar cutting block tongue to the upper surface of talus) by removing the tibial resection block or per fluoroscopy (lateral view).

Several attachments are available for Newdeal® saw blades:
- Aesculap® attachment (309 622)
- AO Synthes® attachment (309 623)
- Stryker® attachment (309 624)
- Conmed Linvatec® attachment (309 627)
- Stryker® attachment (309 626)
### Posterior and collateral cuts

- The appropriate size of the talar cutting guide* is selected as follows:
  - medial side: to resect 2 mm of bone (parallel cut);
  - lateral side: to resect 1-3 mm of bone (e.g. 1 mm on posterior aspect and 2-3 mm on anterior aspect, as given by the anatomy of the talar body).

- The selected talar cutting guide is placed on the flat surface of the talus maintaining the hooks carefully positioned on the posterior aspect of the talus; the resection guide becomes in proper contact to the resection surface of the talus.

- While the foot is brought to a neutral position, the handle of the cutting guide should meet the second ray.

- 2 to 4 pins are used for fixation of the cutting guide to the talus.

- The posterior cut is made through the posterior slot using the oscillating sawblade.

* 309 360 to 366 for the right foot
  309 370 to 309 376 for the left foot

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**NOTE**

If there is any doubt about the selected size, the depth of the tibia can be measured now and the talus is selected according to the measured size of tibia.

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**NOTE**

In case of osteophytes or thick cartilage layer left on posterior talus, a chisel is used to remove it. The tibial impactor (119 751) can be used to get the cutting guide fitted firmly to the talar resection surface.

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**NOTE**

Number and length of pins may be selected according to the quality of bone to obtain an appropriate fixation. If necessary, the position of the cutting guide can be checked by fluoroscopy (e.g. proper fit of hooks on posterior aspect of talus and cutting guide on resection surface); the posterior peaks on the flat talar horizontal surface indicate the enter of the talar component with regards to its antero-posterior position.
• Then, medial and lateral cuts are made using the reciprocating saw, paying attention that the sawblade follows strictly the cutting guide.
  – medial size: approximately 6 mm deep,
  – lateral size: approximately 8 mm deep.

• The resected bone is removed with a rongeur.
• Remaining bony and capsular structures on posterior aspect are carefully removed.

Anterior cut
• The provided talar reamer (diam. 6 mm 309 200) is used to make the anterior cut through the slot, and the created step is debrided with a rongeur.

1 Attention should be paid to keep the reamer perpendicular to the slot and to go as deep as possible as allowed by the end-stop. The flange of the reamer should sit properly and perfectly perpendicular to the cutting guide.

NOTE
If necessary, a chisel might be used to finish the cut at its medial and lateral borders. In order to make further talar trial impaction easier, it may be helpful to slightly resurface the postero- lateral corner of the talus, according to the cutting guide.

NOTE
A chisel is used to mobilize the medial and lateral resections of the talus if necessary (e.g. hard bone), the posterior corner of collateral cuts might be smoothen with a chisel or rongeur to allow proper insertion of the talar trial.

NOTE
In case of hard bone, more than one lateral movement should be performed.
7. Checking of the cuts, alignment and stability

- After having removed the Hintermann® distractor (119 664), the 12 mm thick spacer (309 608) representing the thickness of the tibial and talar components and the thinnest 5 mm inlay is inserted into the created joint space. While the foot is held in neutral flexion position, it allows to check the following points:

1. If insufficient quantity of bone has been resected.

   If the spacer cannot be properly inserted into the joint space, and if there is no obvious contracture of the remaining posterior capsular, additional bony resection might be considered. In most instances, such additional resection should be done on tibial side. The tibial cutting block is repositioned using the same fixation holes for the pins. The distal resection block is moved proximally as desired, and a new cut is performed with the saw blade. Alternately, the tibial revision cutting guide (119 641) can be used on the tibial cut to remove exactly 2 mm of bone.

2. If the achieved alignment is inappropriate.

   If the alignment is not appropriate, and if an associated deformity of the foot itself (e.g. varus, valgus heel) can be excluded, a corrective cut should be considered. In most instances, the resection should be done on tibial side. The desired angular correction on tibial resection cutting is made, and the tibial cutting block is repositioned using other fixation holes for the pins. The distal resection block is moved proximally or distally to match with the height of the original cut such as an angular bony resection will result.

3. If the medial and lateral stability are inappropriate.

   If the ankle is not stable on both sides, the use of a thicker inlay might be advised. If the ankle is not stable on one side, a release of the contra-lateral ligaments, and/or ligament reconstruction on affected side should be considered. Ligament reconstruction is better done once the definitive implants have been inserted, and if there is still an obvious instability.

Three cases:
8. Assessment of the tibial size

- The tibial depth gauge (309 607) is used to determine the size of tibial implant.
- The gauge is inserted with the appropriate side (right/left) against the tibial surface, and the posterior edge is hooked on the posterior border of the tibia. The size to be selected can be read from the scale on depth gauge, located on its upper side (tibia side).

*NOTE* if the anterior border of the tibia is between 2 marks, the biggest size should be selected between both. The anterior tibia might be shaped to the indicated mark to allow appropriate positioning of the tibial component (e.g., no medial or lateral gapping that may irritate soft tissues). The curved chisel (997 034) can be helpful for this procedure.

The talar size should not be higher nor smaller than 1 size than the size of the tibial component, e.g., if tibial component size is 2, talar component size must be 1, 2, or 3.

9. Finalisation

- On medial and lateral sides, the cuts are finalized using a chisel to make an almost horizontal cut along the base of the cuts previously done. Thereby, this will avoid extended loss of bone stock and potential damage of the vascular supply of the talus.
- The medial and lateral gutters are cleaned using a rongeur.
- The remaining bone and capsule of the posterior compartment are removed.

*NOTE* The posterior capsule should be removed completely until fat tissue and tendon structures are visible, in order to achieve full dorsiflexion.
10. Insertion of trial components

10.1 Talar trial at first
- A specific holder (309 697) can be used to bring the talar trial onto the talar cuts.
- The selected talar trial (309 680-686 for right side / 309 690-696 for left side) is inserted using the specific impactor (309 699). The window on the posterior aspect of the trial allows to check its proper fit to the posterior resected surface of the talus.

10.2 Tibial trial
- The tibial trial (119 690-119 699 / 119 778-779 / 119 646-647), as selected before, is inserted.
- Attention should be paid to get the tibial component in close contact with the medial malleolus.

10.3 Trial inlay
- The 5 mm trial inlay (119 665) is inserted and the Hintermann® distractor is removed; if not enough soft tissue tension can be achieved, the 6 mm, 7 mm or 9 mm trials (119 666 / 119 667 / 119 669) are inserted.
Checking

• It is highly recommended to use fluoroscopy to check the position of implants while the foot is held in neutral position, particularly:

a. Appropriate length of tibial component, i.e. its posterior border should be aligned with the posterior aspect of the tibia, thereby the tibial surface is fully covered.

b. Proper fit of tibial component to the tibial surface.

c. Proper fit of the posterior edge of talar component to the posterior surface of the talus.

d. Point of contact of talar component to the tibial component.

This contact point should be positioned between 40 and 45% of tibial component when the anterior border is taken as 0% and the posterior border as 100%, respectively. If the point of contact is too posterior, ligament balance would not be able to be achieved.
11. Anterior cut of the talus

- If proper position of the talar trial has been achieved, resection of the anterior surface of the talus is done, using a rongeur.
- The Hintermann® distractor is mounted using the remaining k-wires.

12. Drilling of the peg holes

- The talar drilling guide (same size as the talar trials: 309 300-306) is screwed to the talar trial still in place.
- 2 holes are made with the ø4.5 mm peg drill (309 309). The assembly is then removed.

NOTE

The bony surfaces are carefully checked. If there are any cysts, they should be removed with a curette, and filled with cancellous bone taken from the removed bony material. If sclerotic bone is left on the surfaces, drilling with a 2.0 mm drill is advised.
13. Implants insertion

- The definitive implants are inserted as follows:

13.1 Talar component
- The talar component is implanted using the implant holder (119 662) such as the pegs can glide into the 2 holes; hammer and impactor (119 609) are used to get a proper fit of the component to the bone.

13.2 Tibial component
- The tibial component is inserted using the implant holder (119 662) along the medial malleolus until proper fit to the anterior border of the tibia is achieved. Hammer and impactor (119 751) might be used for impaction.
  
  To avoid any contact between the metallic surfaces, retrograde insertion on the trial inlay is advised.
Inlay

- The inlay (same size as the talar component) is inserted; the implant holder may be used (309 661).

As the contact surface on the talus is conical, there is a difference between the radii on medial and lateral aspects of the talus. So adequate insertion of the inlay is mandatory! The markers for right and left ankle on anterior aspect of the inlay must be respected.

Checking

- The Hintermann® distractor is removed, and achieved stability and motion are checked clinically.
- It is also highly recommended to check the position of the implants by fluoroscopy, as described for the trial implants. Please note that polyethylene inlays embed 2 metallic rods that can be seen fluoroscopically.

NOTE

While the foot is moved in dorsiflexion with maximal strength, settling of the implant might be improved, and remaining soft tissue contracture on posterior aspect of the ankle might be released.

NOTE

Fluoroscopy allows also to detect any remaining bony fragments or osteophytes that could be a potential source of pain or motion limitation.
14. Optional Tibial Screw fixation

- Screw fixation of the tibia may be used if there is any doubt on enough stability against rotational and translational forces during the osteointegration process.
- The holes are drilled with the 2.5 mm drill (119 611) using the drilling guide ø2.7 mm (159 127).
- In order not to hinder the initial settling process of the implant, the holes are drilled at the cranial aspect of the 2 oval holes of tibial component, and slightly upwards.
- The screws are inserted and tightened until contact to the implant is obtained. Excessive tightening of the screws should be avoided in order not to create a tilting moment on the implant.

15. Wound closure

- Wound closure is obtained by suture of the tendon sheath and retinaculum, respectively, and the skin.
- Careful dressing is made to avoid any pressure to the skin.
- A splint is used to keep the foot in neutral position.

16. Postoperative care
(Recommended by Prof. B. Hintermann, Switzerland)

- Dressing and splint are removed and changed after 2 days.
- When the wound condition is dry and proper, typically 2 to 4 days after surgery, the foot is placed in a stabilizing cast or walker that protect the ankle against eversion, inversion, and plantar flexion movements for 6 weeks.
- Weight bearing is tolerated. Usually, full weight bearing is achieved after 1 week.
- A rehabilitation program should be started for the foot and ankle after cast or walker removal, including stretching and strengthening of the triceps surae.
- First clinical and radiological control is made at 6 weeks, to check wound status, osteointegration and position of the implants.
- The patient should be advised to wear a compression stocking to avoid swelling for further 4 to 6 months.

NOTE
A controlled trial of 120 cases has shown no evidence of increased primary stability with additional tibial screw fixation. (B. Hintermann, unpublished data.)
INSTRUCTIONS FOR USE
Hintegra® - HINTERGA® SENSITIVE STERILE MEDICAL DEVICES - SINGLE USE

In accordance with EEC directive 93/42 relative to medical devices, the surgeon must be handed and/or implanted by WELL-TRAINED, QUALIFIED PERSONS, AWARE OF THESE DIRECTIONS FOR USE.

1. Description of the medical devices:
The Hintegra® and Hintegra® Sensitive ankle prosthesis exist in different sizes. The prosthesis is composed of a tibial component, a talar component and an intermediary sliding core. Optional fixation screws are also provided.

2. Hintegra®:
- Both Hintegra® tibial and talar components are made out of Cobalt Chrome alloy (CoCr) according to NF ISO 5832-4 and ASTM F75, with a porous titanium and hydroxyapatite coating (Ti + HAP). The intermediary sliding core is made out of UHMW Polyethylene, according to ISO 5834-2 and ASTM F648. Fixation screws are made of stainless steel according to ISO 5832-9 and ASTM F1586.

3. Hintegra® Sensitive:
- Both Hintegra® Sensitive tibial and talar components are made out of Cobalt Chrome alloy (CoCr) according to NF ISO 5832-4 and ASTM F75, with a Titanium Nitride coating (TiN) and with a porous titanium and hydroxyapatite coating (Ti + HAP).
- Both Hintegra® Sensitive tibial and talar components must be used with the intermediary sliding core labeled « Hintegra® sensitive compatible ».
- The intermediary sliding core labeled « Hintegra® sensitive compatible » is intended to be used with Hintegra® prosthesis and Hinterga® Sensitive prosthesis. It is made out of UHMW Polyethylene, according to ISO 5834-2 and ASTM F1586. Fixation screws are made of titanium alloys according to ISO 5832-3 and ASTM F138.
- The tibial and talar components, as well as the intermediary sliding core, are delivered sterile.

4. Indications:
- Systemic causes of arthritis of the ankle (e.g. rheumatoid arthritis, hemochromatosis)
- Primary arthritis (e.g. degenerative disease)
- Secondary arthritis (e.g. posttraumatic, infection, avascular necrosis)
- Severe malalignment
- Salvage for failed total ankle replacement**
- For non-union and malunion of ankle arthrodesis**
- *If 2/3 malunion of the talus is preserved
- *If bone stock is sufficient The patient’s joint must be anatomically and structurally suited to receive the selected implant(s). The size of both Hintegra® intermediate sliding core and talar components must not be implanted in a patient weighing more than 65 kilos.

5. Hintegra® sensitive:
- The prosthesis Hintegra® sensitive is designed to minimise the risks of allergy to chrome-cobalt alloy.

6. Centre-indications:
- Relative contraindications:
  - Severe osteoporosis
  - Immunosuppressive therapy
  - Absolute Contraindications:
    - Infection
    - High-demand sporting activities (e.g. contact sports, jumping)
    - Suspected or documented metal allergy or intolerance
    - Avascular necrosis of the talus/tibia of > 1/2
    - Severe malalignment
    - Severe instability
    - Diabetic symptom
  - *If surgery is surgically contraindicated

The size 0 of both Hintegra® intermediate sliding core and talar components must not be implanted in a patient weighing more than 65 kilos.

7. Warnings:
- Severe post-operative complications may occur from use of the implant in a patient who:
  - Lacks good general physical condition;
  - Has severe osteoporosis;
  - Demonstrates physiologic or anatomical anomalies;
  - Has immunologic responses, sensitisation, or hypersensitivity to foreign materials;
  - Is subject to metabolic disorders;
  - Moreover, joint replacement may be contraindicated where there is severe deformity.

8. Precautions for use:
- Physician must determine if implant is appropriate for patients who have any of the following conditions:
  - Drug and/or alcohol and/or smoke and addiction and/or abuse;
  - Infection disease;
  - Malignancy;
  - Local bone tumors;
  - Systemic or metabolic disorders or replacement;
  - Compromised wound healing;
  - Obesity;
  - Demonstrated psychological instability, displayed a lack of understanding or inappropriate attitude;
  - Unwillingness to accept the possibility of multiple surgeries for revision or replacement;
  - Lack of understanding that a metallic implant is not as strong as normal healthy bone and will bend, loosen, or fracture if excessive demand is placed on it;
  - Lack of understanding that their prooperative capacity may not be fully recovered even after successful implantation;
  - Care must be taken that the correct and appropriate size implant is used in conjunction with the correct instrumentation and trial components.
  - Definitive implants and trial components manufactured by Newdeal must not be used in conjunction with those of any other manufacturer as component parts may not be compatible.

- Knowledge of surgical techniques, proper reduction, selection, and placement of implants, and post-operative patient management are considerations essential to a successful outcome.

- In the presence of severe and progressive instability condition, the procedure should be carried out only after consultation with the surgeon. The patient should be fully informed of the risks, complications, and potential adverse effects associated with the procedure.

- The limb must be immobilized for 6 weeks after surgery. The patient must return for control after 6 weeks and 3 months post-surgery. The rehabilitation must be carried out under the guidance of a physical therapist.

9. Use of the implant:
- The tibial and talar components, as well as the intermediary sliding core are sterile.

10. Product information / Liability:
- Newdeal, an Hinterga® LifeSciences Company, has exercised reasonable care in the selection of materials and the manufacture of these products, and warrants that the products are free from manufacturing defects. Newdeal excludes all warranties, whether expressed or implied, including but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Newdeal shall not be liable for any accidental or consequential, loss, damage or expense, directly or indirectly arising from use of this product. Newdeal neither assumes nor authorizes any person to assume for it any other or additional liability or responsibility in connection with these products. Newdeal intends that this device should be used only by physicians having received proper training in orthopedic surgery technique for use of the device.

AVERTISSEMENT: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

INFORMATION: Should any information regarding the products or their uses be required, please contact your representative or distributor or directly contact the manufacturer.

Last revision: 01/15/2010.
## References

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Surgical technique • Hintegra®
PRODUCTS FOR SALE IN EUROPE, MIDDLE-EAST and AFRICA ONLY
### Other instruments

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### Trial inlays

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**Hintegra® Regular Prosthesis**

**Hintegra® Sensitive Prosthesis**

*Technique opératoire Hintegra®*  
PRODUITS DESTINÉS À LA VENTE UNIQUEMENT EN EUROPE, AU MOYEN-ORIENT ET EN AFRIQUE
The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.

**WARNING:**
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**Registration numbers mentioned on this document are CE marked according to European council directive 93/42/EEC on medical devices, unless specifically identified as “NOT CE MARKED.”

**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.

**Always refer to the appropriate instructions for use for complete clinical instructions.

**Non contractual document.**

All the references numbers mentioned on this document are CE marked according to European council directive 93/42/EEC on medical devices, unless specifically identified as “NOT CE MARKED.”

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**Non contractual document.**

### Tibial trials and tibial Hintegra® regular and Sensitive components

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### Talar trials and talar Hintegra® regular and Sensitive components

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### Optional tibial cortical screws Hintegra®

**Sensitive prosthesis (Titanium)**

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### Optional tibial cortical screws Hintegra®

**Regular prosthesis (Stainless steel)**

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**Distributed by:**

**Integra LifeSciences Services (France) SAS**

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