

Strada Regina
CH - 6874 Castel San Pietro - Switzerland
Phone +41 91 696 60 60 - Fax +41 91 696 60 66
info@medacta.ch – www.medacta.com






Manufactured by:
Medacta International SA
CH-6874 Castel San Pietro - Switzerland

AMIS SHOE

CAUTION

For a U.S. specific package insert, please go to www.medacta.com or call toll free 800-901-7836.

SYMBOLS / SIMBOLI / PICTOGRAMMES / PIKTOGRAMME / PICTOGRAMAS / PICTOGRAMAS / PICTOGRAMMES / ΕΙΚΟΝΟΣΥΜΒΟΛΑ

	Consult instructions for use / Consultare le istruzioni di utilizzo / Gebruiksaanwijzing / Bitte lesen Sie die Gebrauchsanweisung / Consulte las Instrucciones antes de su uso / Consulte as instruções de uso / Consultez les instructions d'utilisation / Οδηγίες χρήσης
	Store in a dry place / Conservare in luogo asciutto / Droog bewaren / Trocken aufbewahren / Conservar en lugar seco / Conservar em local seco / Conserver au sec / Φυλάσσετε σε ξηρό χώρο
	Lot number / Numero di lotto / Nummer van de partij / Waren-Lot-Nummer / Número de lote / Número de lote / Numéro de lot / Αριθμός παρτίδας
	Reference number / Riferimento commerciale / Handelsreferentie / Referenznummer / Numero de Referencia / Referência comercial / Référence commerciale / Νούμερο παραπομπής
	Manufacturer / Produttore / Fabrikant / Hersteller / Fabricante / Fabricante / Fabricant / Κατασκευαστής

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1. GENERAL

Before any THA surgery, the surgeon must be familiar with the AMIS operative technique.

2. AMIS SHOE INTENDED USE

The AMIS shoe is a reusable device that must be used only with the AMIS mobile leg positioner for a stable patient positioning during Hip Arthroscopic procedures. All structures of the AMIS shoe (reference 01.15.10.0315) shown below, are part of quoted reference.

3. AMIS SHOE DESCRIPTION



NOTE: The decision of when to use the small foot adaptor is up to the surgeon. While doing it, please consider the dimensions of the small foot adaptor:

I. 76 mm in the calf area

II. 78mm in the heel area

III. 83 mm in the foot area, near the toes



4. WARNINGS AND PRECAUTIONS

The success of the operation depends on compliance with the operative technique supplied, and the proper use of the instrumentation supplied.

For THA procedures, please refer to the dedicated AMIS surgical technique.

When preparing the Patient's foot it's important not to overtighten the fixation buckle for the AMIS shoe to avoid excessive pressure on the patient's foot (see AMIS SHOE ASSEMBLY paragraph).

5. SURGICAL TECHNIQUE

For THA procedures, the surgeon should be fully familiar with the AMIS surgical technique. Please refer to the AMIS surgical Technique for supplementary information.

6. INSTRUCTIONS FOR USE

AMIS SHOE ASSEMBLY

STEP 0

Bolster the foot appropriately before placing it into the AMIS shoe (the image on the right is an example of how to bolster the foot).



OPTION FOR SMALL FOOT: ASSEMBLY WITH ADAPTOR

When the Small foot adaptor is deemed necessary, simply insert it into the AMIS shoe (2) and proceed as described in STEPS 1- 4.



CAUTION:

Correctly position the Small Foot Adaptor by placing the part with a small foot printed on it, internally and externally(3) (4), in contact with the patient's sole of the foot. Additionally, check that the longer part of the Small Foot Adaptor is facing upwards (2) .

**STEP 1**

Insert the bolstered foot into the AMIS shoe. The patients heel needs to be in contact with the AMIS shoe.

Fix-it by fastening the Fixation buckle:

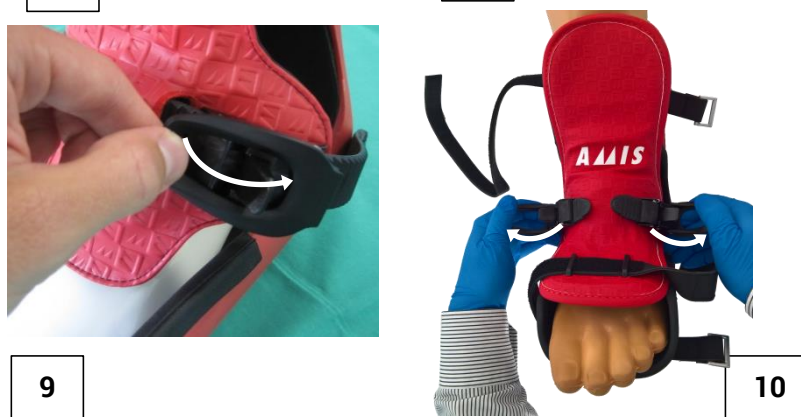


Introduce the strap into the buckle(6)(7). Repeat the procedure for both the Fixation buckles (8).



To tighten it, pull the buckle as shown in picture (9). **The padded foot holder should be centered** in order to apply an equal pressure all over the foot. If necessary adjust it with the Fixation buckles on both sides (10).

WARNING: do not overtighten the fixation buckle to avoid excessive pressure on the patient's foot.



STEP 2

At this time, the Foot strap can be tightened, as shown in pictures (11)(13)(14).



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Note: the stability of the foot is not influenced by this strap. Do not overtighten it.



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STEP 3

At this time, the Tibial strap can be tightened, as shown in pictures (15)(16)(17).



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Note: the stability of the foot is not influenced by this strap. Do not overtighten it.

At this time check that the foot is stable but **without excessive pressure applied** on it. A finger should easily pass between the foot and the shoe at malleolus level (18). To reach the perfect stability apply/release the pressure through the Fixation buckles.

The foot is now fixed to the AMIS shoe.



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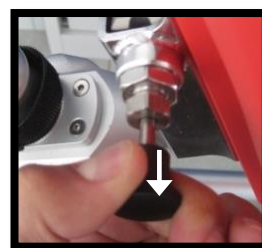
STEP 4

Slide the shoe onto the traction arm of the AMIS Mobile Leg Positioner (20) and lock the system with the black plunger (21).

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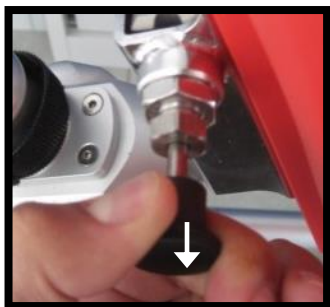
To check the stability of the foot inside the AMIS shoe, apply some traction with the AMIS Mobile Leg Positioner and check that the heel does not move.



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7. AMIS SHOE DISASSEMBLY AND CLEANING

When the surgery is finished, the AMIS shoe must be disassembled from the AMIS Mobile Leg Positioner BEFORE disassembling the Leg Positioner from the operating table (24) (25). Simply Unlock the black plunger and remove the AMIS shoe from the traction arm of the AMIS leg. Positioner.



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STEP 1

Remove the Tibial and the Foot straps as shown in the pictures (26) (27) (28) (29) (30).



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Step 2

Release the Fixation buckle by pressing on its overhang, as shown in the picture (31) (32).

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8. STORAGE

After removing the AMIS shoe from the patient's foot, store it with the Small Foot adaptor to avoid losing it (33). Follow the general rules for cleaning operating tables.

NOTE: Do not autoclave the AMIS shoe (Ref. 01.15.10.0315).

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Last update: January 2020

