

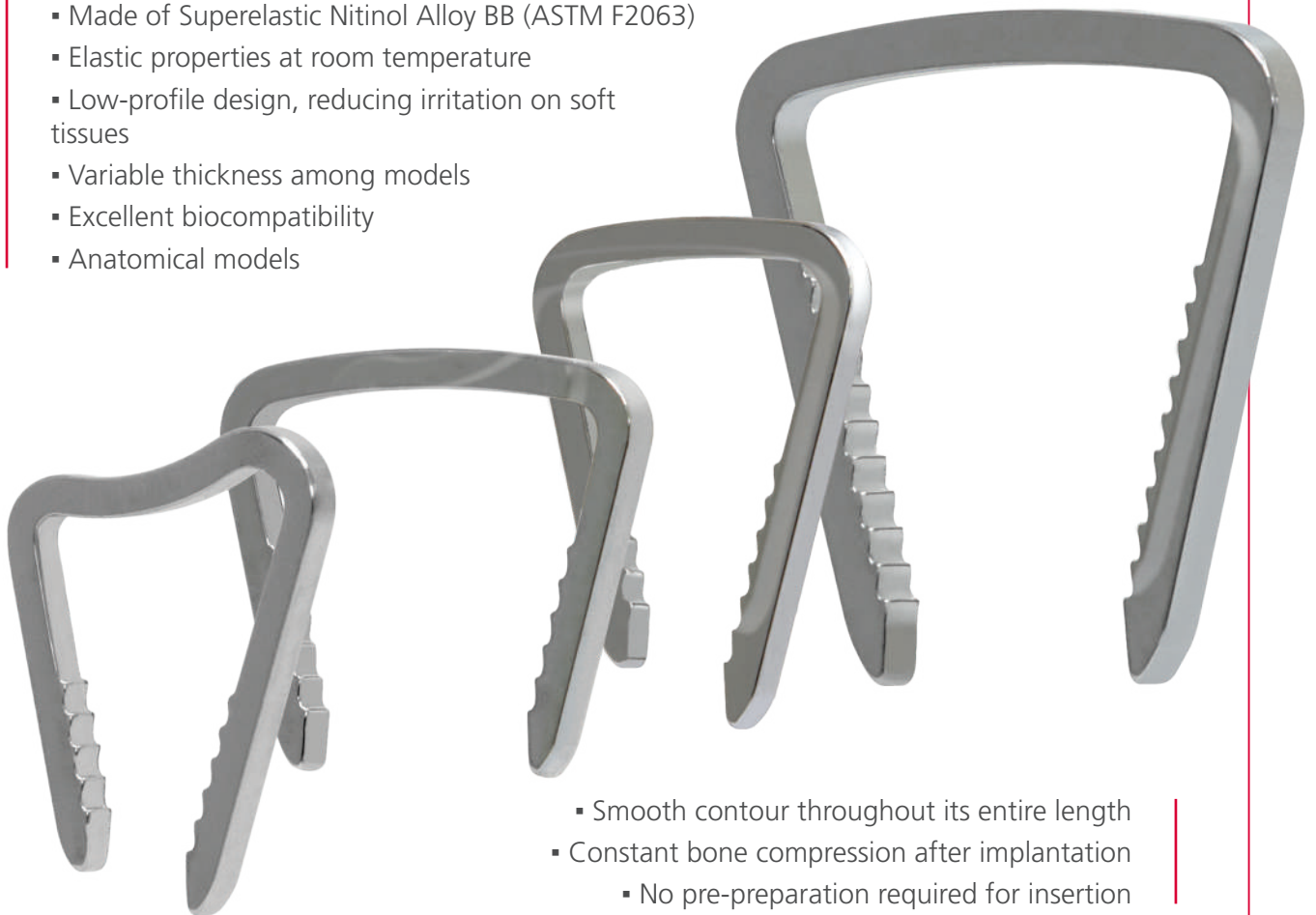
## NitFix Razek

Developed for fixation and stabilization of the bones of the upper and lower extremities, due to its superelastic property and its specific geometry, the NitFix Razek allows the surgeon to perform the bone consolidation of the fragments, in the correct anatomical position. It is an implantable component that provides a means of osteosynthesis in the treatment of fractures, osteotomies and arthrodesis.

Unlike the static compression promoted by rigid fixation implants, where over time the viscoelastic properties of the bone lead to tension relaxation and thus reduce the initial compression of the implant, NitFix Razek implants are capable of maintaining continuous compression after implantation. As a result, the clamp will promote dynamic reduction and compression of the bone fragments, keeping them together until their consolidation.<sup>[1]</sup>

### TECHNICAL SPECIFICATIONS

- Several sizes and geometries to adjust to the different anatomical structures of foot and hand bones
- Made of Superelastic Nitinol Alloy BB (ASTM F2063)
- Elastic properties at room temperature
- Low-profile design, reducing irritation on soft tissues
- Variable thickness among models
- Excellent biocompatibility
- Anatomical models

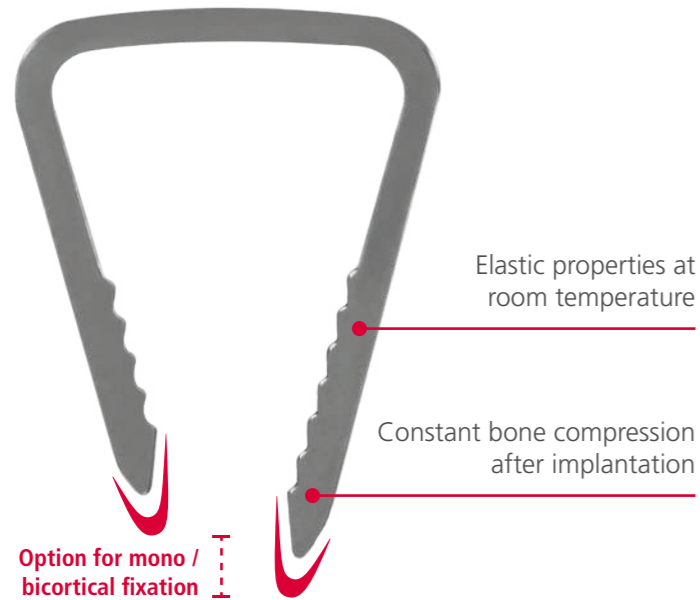


- Smooth contour throughout its entire length
- Constant bone compression after implantation
  - No pre-preparation required for insertion

<sup>[1]</sup> Schipper, O. N., & Ellington, J. K. (2019). Nitinol Compression Staples in Foot and Ankle Surgery. *The Orthopedic clinics of North America*, 50(3), 391–399. <https://doi.org/10.1016/j.ocl.2019.02.003>

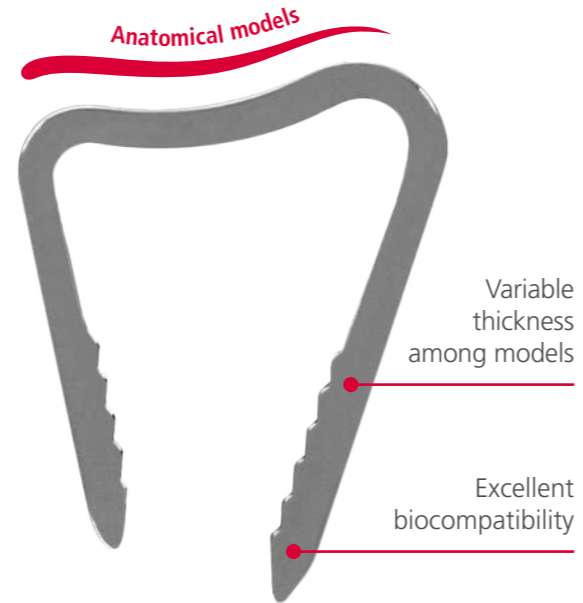
## AGS

NitFix models with reduced geometry, designed specifically for the forefoot, midfoot, hand, and wrist regions



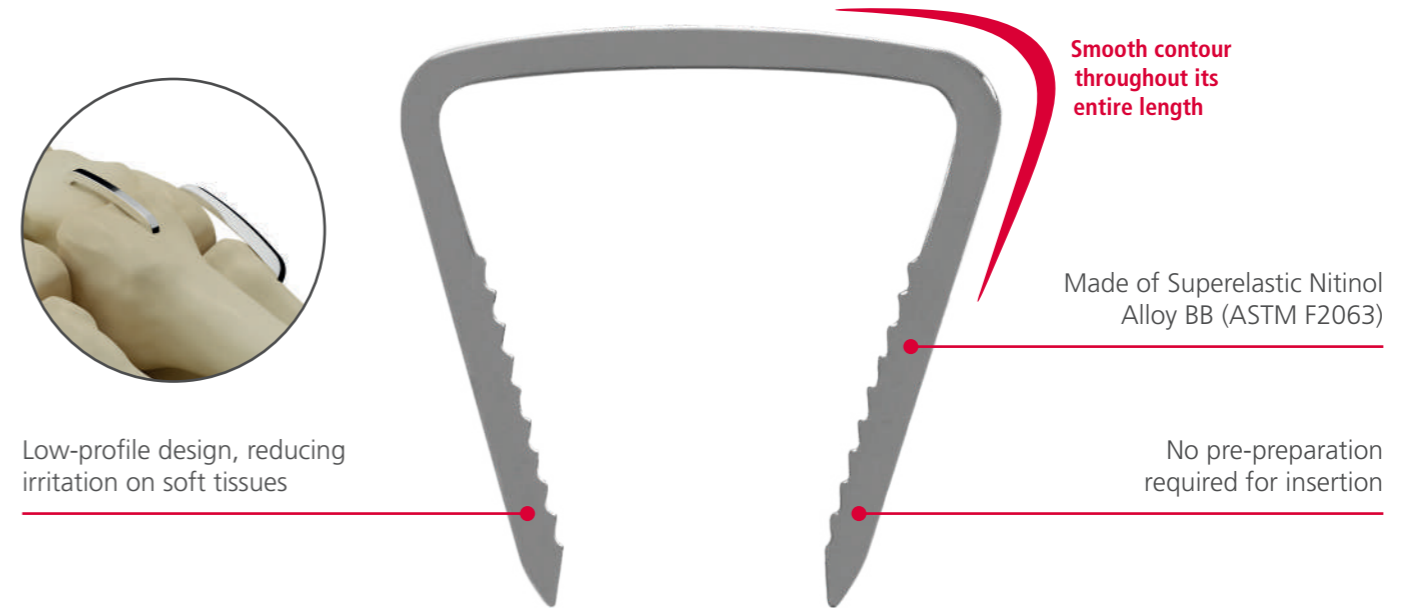
## AGA

NitFix models with anatomical geometry, designed specifically for the fifth metatarsal region



## AGL

NitFix models with reinforced geometry, designed specifically for the hindfoot region



### SUPERIOR DYNAMIC COMPRESSION FORCE OF OVER 1.100 N

Graphic Design	Model Description	Code	Thickness
	NitFix Razek 1.5 x 9 x 7 x 7 (AGS 09-07-07)	500100010	1.5 mm
	NitFix Razek 1.5 x 9 x 10 x 10 (AGS 09-10-10)	500100020	
	NitFix Razek 1.5 x 11 x 10 x 10 (AGS 11-10-10)	500100030	
	NitFix Razek 1.5 x 11 x 15 x 13 (AGS 11-15-13)	500100040	
	NitFix Razek 1.5 x 13 x 10 x 10 (AGS 13-10-10)	500100050	
	NitFix Razek 1.5 x 13 x 15 x 13 (AGS 13-15-13)	500100060	
	NitFix Razek 1.5 x 15 x 12 x 12 (AGS 15-12-12)	500100070	1.5 mm
	NitFix Razek 1.5 x 9 x 12 x 10 (AGA 09-12-10)	500100150	
	NitFix Razek 1.5 x 11 x 12 x 10 (AGA 11-12-10)	500100160	
	NitFix Razek 1.5 x 11 x 15 x 12 (AGA 11-15-12)	500100170	2.0 mm
	NitFix Razek 2.0 x 15 x 15 x 15 (AGL 15-15-15)	500100080	
	NitFix Razek 2.0 x 18 x 15 x 15 (AGL 18-15-15)	500100090	
	NitFix Razek 2.0 x 18 x 18 x 15 (AGL 18-18-15)	500100100	
	NitFix Razek 2.0 x 18 x 18 x 18 (AGL 18-18-18)	500100110	
	NitFix Razek 2.0 x 20 x 15 x 15 (AGL 20-15-15)	500100120	
	NitFix Razek 2.0 x 20 x 20 x 20 (AGL 20-20-20)	500100130	
NitFix Razek 2.0 x 25 x 20 x 20 (AGL 25-20-20)	500100140		



# NitFix Razek Instruments

Provides the surgeon with the tools needed to quickly and accurately deploy NitFix Razek.



## INSTRUMENTS

- NitFix Template - Code: 490060010
- AGS/AGA Drilling Guide 9 - Code: 490060020
- AGS/AGA Drilling Guide 11 - Code: 490060030
- AGS Drilling Guide 13 - Code: 490060040
- AGS Drilling Guide 15 - Code: 490060050
- AGL Drilling Guide 15 - Code: 490060060
- AGL Drilling Guide 18 - Code: 490060070
- AGL Drilling Guide 20 - Code: 490060080
- AGL Drilling Guide 25 - Code: 490060090
- FastFit Mandril - Code: 490061040
- AGS/AGA Bone Bit (2 units) - Code: 490061050
- AGL Bone Drill (2 units) - Code: 490061060
- AGS/AGA Inserter - Code: 490060120
- AGL Inserter - Code: 490060130
- AGS/AGA Impactor - Code: 490060140
- AGL Impactor - Code: 490060150
- AGS/AGA Positioning Pin (2 units) - Code: 490060100
- AGL Positioning Pin (2 units) - Code: 490060110
- NitFix Cable - Code: 490060160
- Adson Serrated Forceps - Code: 490060180
- Depth Meter 30 mm - Code: 490060170
- Box with internal divisions for storage of NitFix Instruments - CXIM 013 - Code: 700437100

**Note:** Implantable components are not included in the kit and must be acquired separately.

# NitFix Razek Usage Guidelines

1 | After incision, prepare the bone surface;

2 | Use the **NitFix Template** to assist in selecting the appropriate NitFix Razek model for implantation. The NitFix Template features selection guides corresponding to the width of all available NitFix Razek models;

3 | Select the desired NitFix Razek model;

**Note:** NitFix Razek models come in different thicknesses and widths and are divided into three groups: AGS, AGA, and AGL. The instruments for NitFix Razek implantation are identified by color-coding, with instruments for AGS and AGA groups identified in green, and instruments for AGL group identified in blue.

Instrument	Code
NitFix Template	490060010



4 | Choose the appropriate **Drilling Guide** for the chosen NitFix Razek model and attach it to the **NitFix Cable**. Position the Drill Guide at the desired location;

**Note:** The Drill Guides feature the widths of all available NitFix Razek models and are identified by color-coding.

FastFit Razek Model	Code
AGS/AGA Drilling Guide 9	490060020
AGS/AGA Drilling Guide 11	490060030
AGS Drilling Guide 13	490060040
AGS Drilling Guide 15	490060050
AGL Drilling Guide 15	490060060
AGL Drilling Guide 18	490060070
AGL Drilling Guide 20	490060080
AGL Drilling Guide 25	490060090
NitFix Cable	490060160





5 | Using a drill, perform the first drilling using the appropriate **Bone Drill** for the chosen NitFix Razek model;

Instrument	Code
AGS/ AGA Bone Bit	490061050
AGL Bone Drill	490061060
FastFit Mandril	490061040



6 | Remove the Drill Guide and check the depth of the drilling using the **Depth Meter**;

Instrument	Code
Depth Meter 30 mm	490060170



7 | Insert the appropriate **Positioning Pin** for the chosen NitFix Razek model under the Drill Guide to maintain the desired distance between the drillings;

8 | Repeat the steps described in items 5 and 6 for the second drilling;

Instrument	Code
AGS / AGA Positioning Pin	490060100
AGL Positioning Pin	490060110



**9** | Select the appropriate **Insertor** for the chosen NitFix Razek model. Adjust the Insertor Limiter according to the width of the chosen NitFix Razek. The Insertor contains a graduated axis that aids in the precise opening of the implant;

Instrument	Code
AGS/AGA Insertor	490060120
AGL Insertor	490060130



**10** | Insert the NitFix Razek onto the tip of the Insertor and rotate it 90° clockwise, so that the implant is parallel to the Insertor;

**11** | Open the Insertor to the position determined by the Insertor Limiter and secure the assembly by screwing the Insertor Fixator;

**Note:** To correctly insert the NitFix Razek, the Insertor should be opened in a way that the legs of the NitFix Razek are perfectly parallel.

**12** | Perform the insertion of the NitFix Razek;

**Note:** After the complete insertion of the NitFix Razek, release the Insertor Fixator and rotate it 90° counterclockwise for removal.



**13** | Position the appropriate **Impactor** for the chosen NitFix Razek model beneath the implant surface and impact it to complete the insertion of the NitFix Razek;

Instrument	Code
AGS/AGA Impactor	490060140
AGL Impactor	490060150



**14** | After implantation, verify the correct positioning of the NitFix Razek using an image intensifier;



**15** | If additional stabilization is required, repeat the steps described in items 2 to 14 for the implantation of a second NitFix Razek.

