

EasyFuse™

Dynamic compression system

Operative technique



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Proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training and experience. Prior to use of the system, the surgeon should refer to the product package insert for complete warnings, precautions, indications, contraindications and adverse effects. Package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the package insert is available on the website listed.

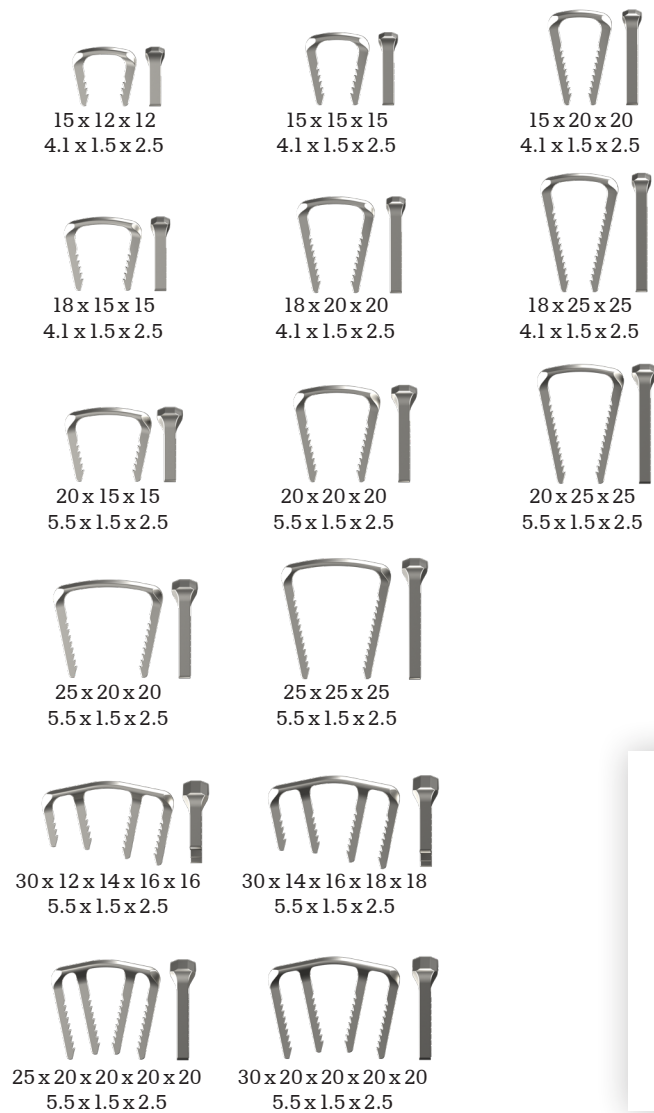
Acknowledgments:

Surgeon design team – The EasyFuse dynamic compression system was developed in conjunction with: John R. Clements, DPM (Roanoke, VA), Kent Ellington, MD (Charlotte, NC), Carroll Jones, MD (Charlotte, NC), John S. Lewis, Jr., MD (Louisville, KY)

Introduction

EasyFuse dynamic compression system is an internal fixation system intended for fractures, osteotomies, and joint arthrodesis of the midfoot and hindfoot. The system is provided as a single-use sterile pack comprising of a bone staple implant and select instruments for implantation. Multiple implants sizes are available consisting of two-leg and four-leg variants with features such as low-profile and wide bridges, as well as multiple leg lengths. Additional instruments are provided in separate, single-use sterile packs. The staple is composed of nickel-titanium (nitinol) alloy per ASTM F2063.

EasyFuse implants are provided pre-loaded on a single-use disposable cartridge. This cartridge is then attached to an inserter creating the assembly used to implant the staple. The implant is designed to provide sustained compression to facilitate bony fusion.



Indications and contraindications

Indications

The EasyFuse dynamic compression system is intended to be used for fracture fixation, osteotomy fixation, and joint arthrodesis of the foot and ankle.

Contraindications

There are no product specific contraindications.

Operative technique

Mid/Hindfoot surgical technique

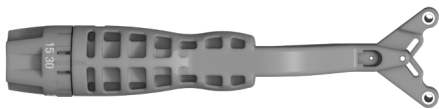
Step 1: Prepare fusion site

Create the osteotomy and/or prepare the fusion site needed to implant EasyFuse.

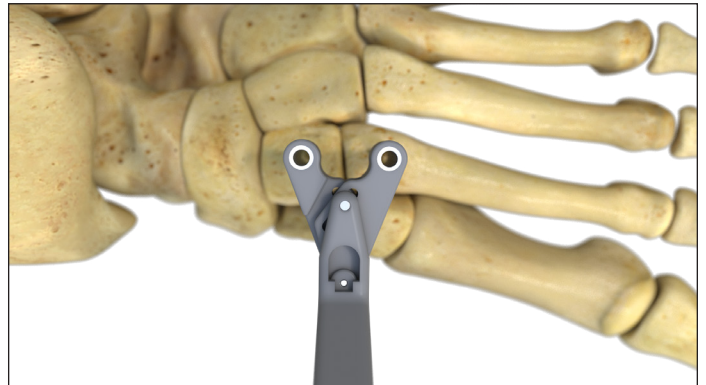


Step 2: Size

Place the Universal Drill Guide perpendicular across the fixation site to determine the appropriate implant size. Rotate the knob clockwise and select the preferred staple size. Notice the distance between drill holes will change as the knob is rotated to each size.



Universal Drill Guide



Step 3: Drill

Use the Drill to create a pilot hole in the bone. Use the laser markings on the Drill to measure the drill depth.

Prior to drilling any additional holes, place a corresponding Locator Pin in the first hole through the drill guide.

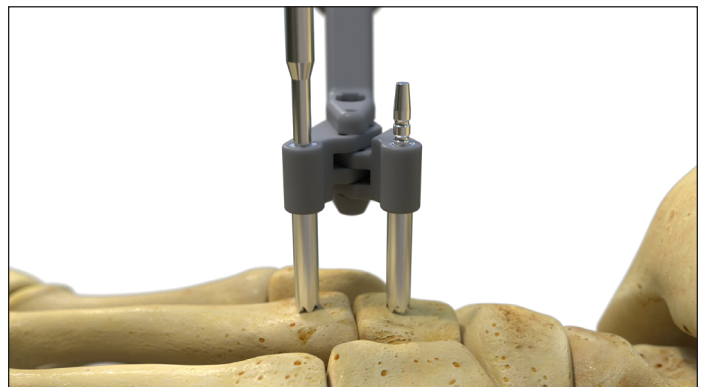
NOTE: Do not use the Drill Guide as a means of achieving compression. Hold compression manually and drill straight into the Drill Guide Sleeves taking care not to create any off-axis torque between drill and sleeve.



Locator Pin



Drill



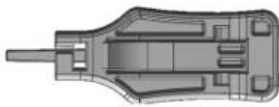
Step 4: Prepare inserter

Place the Universal Implant Inserter into its unlocked position by lifting the lever up.

Assemble the selected implant Cartridge onto the Universal Inserter by aligning the tabs on the implant Cartridge with the grooves of the Universal Inserter and rotating clockwise until locked.

Proceed to press the lever of the Universal Inserter down to its locked position to outwardly displace the legs of the EasyFuse implant.

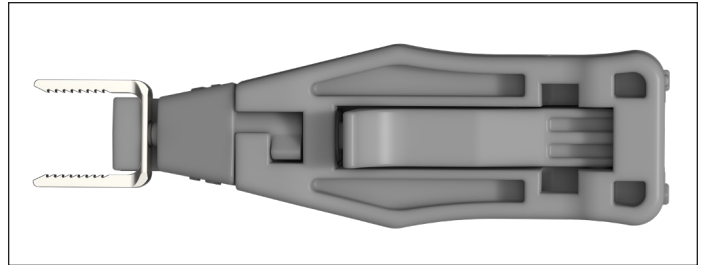
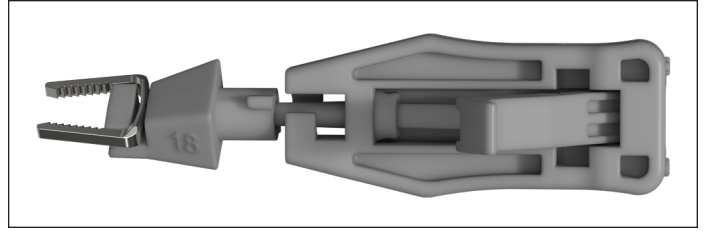
NOTE: Do not press the lever into its locked position until time has come to insert the implant into bone.



Universal Inserter



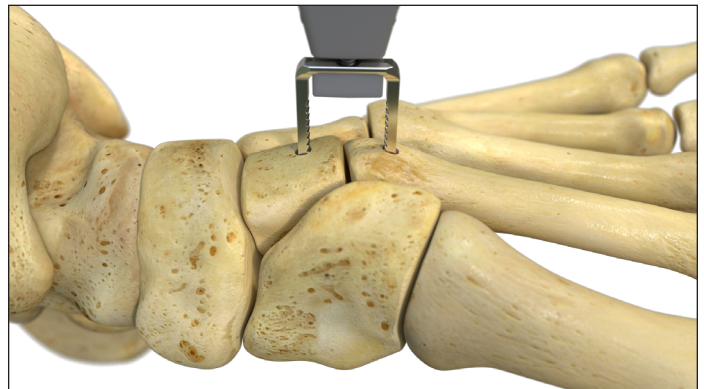
Implant Cartridge



Step 5: Insert implant

Remove the Locating Pins and Drill Guide before inserting the implant.

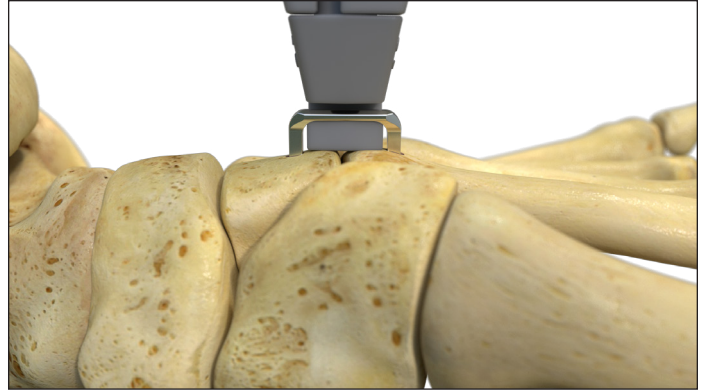
Position the legs of the EasyFuse over the pilot holes and advance the implant into the holes by hand until fully seated.



Step 6: Remove inserter

Unlock the Universal Implant Inserter from the implant by moving the inserter lever to its unlocked position.

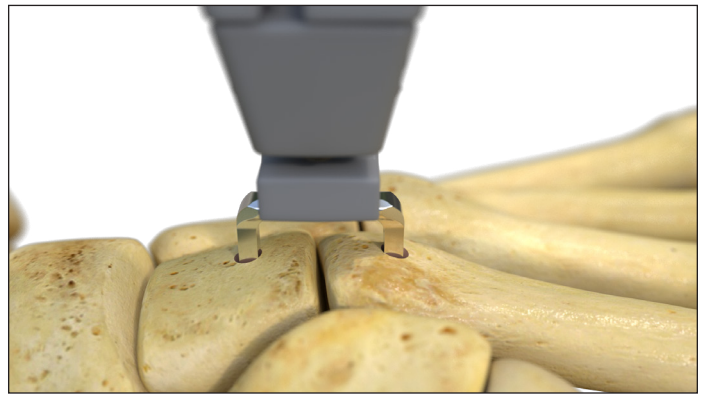
Slide outward or twist counter-clockwise the Universal Inserter to disengage cartridge from implant.



Step 7: Final seat and fluoro check

If necessary, place the implant Cartridge on the EasyFuse bridge and lightly tap with a mallet on the back of the Inserter until the implant is flush to the bone.

Check the final position of the EasyFuse implant under fluoroscopy.



Step 8: Additional implants

Repeat steps 2 through 7 for each additional EasyFuse implant used.

Tip: If placing 2 EasyFuse implants in any orientation other than parallel to one another, stagger the implant placement so the legs do not obstruct one another inside the bone.



4-Leg surgical technique

Step 1: Prepare fusion site

Create the osteotomy and/or prepare the fusion site needed to implant EasyFuse.

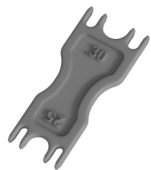


Step 2: Size

Place the 4-leg Sizer perpendicular across the fixation site to determine the appropriate implant size.

Adjust the distance across the Universal Drill Guide to the selected size by rotating the knob clockwise.

Attach the 4-leg Clip to the Universal Drill Guide.



4-Leg Sizer



4-Leg Clip

Step 3: Drill

Place the Universal Drill Guide across the fixation site. Use the Drill to create a pilot hole in the bone. Use the laser markings on the Drill to measure the drill depth.

Prior to drilling any additional holes, place a corresponding Locator Pin in the first hole through the drill guide. Prepare the outer most holes first prior to preparing the inner holes.

NOTE: Do not use the Drill Guide as a means of achieving compression. Hold compression manually and drill straight into the Drill Guide Sleeves taking care not to create any off-axis torque between drill and sleeve.



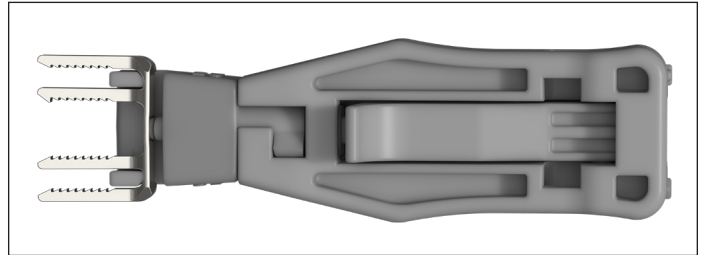
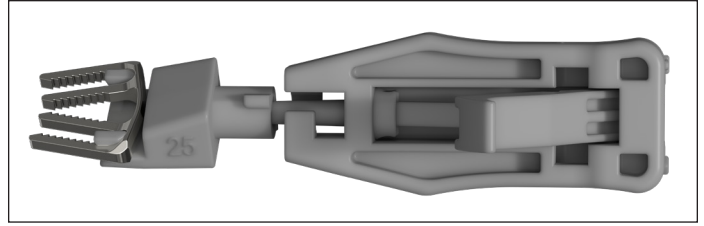
Step 4: Prepare inserter

Place the Universal Implant Inserter into its unlocked position by lifting the lever up.

Assemble the selected implant Cartridge onto the Universal Inserter by aligning the tabs on the implant Cartridge with the grooves of the Universal Inserter and rotating clockwise until locked.

Proceed to press the lever of the Universal Inserter down to its locked position to outwardly displace the legs of the EasyFuse implant.

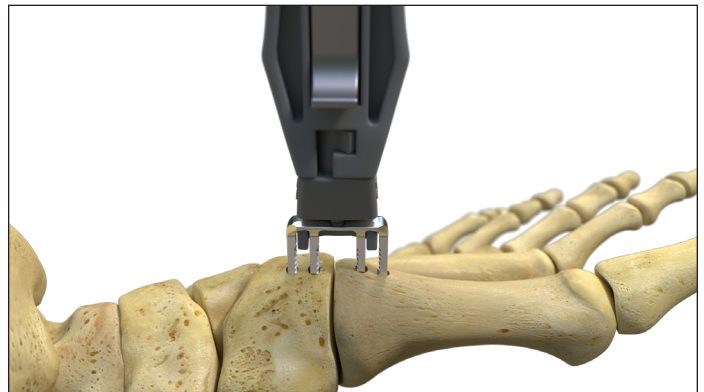
NOTE: Do not press the lever into its locked position until time has come to insert the implant into bone.



Step 5: Insert implant

Remove the Locator Pins and Drill Guide before inserting the implant.

Position the legs of the EasyFuse implant over the pilot holes and advance the implant into the holes by hand until fully seated.



Step 6: Remove inserter

Unlock the Universal Implant Inserter from the implant by moving the inserter lever to its unlocked position.

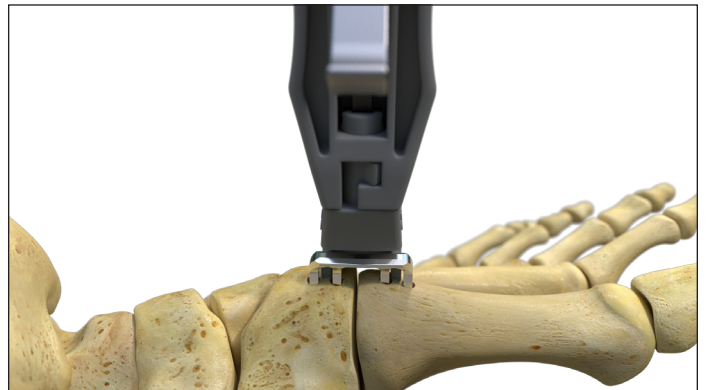
Slide outward or twist counter-clockwise the Universal Inserter to disengage cartridge from implant.



Step 7: Final seat and fluoro check

If necessary, place the implant Cartridge on the EasyFuse bridge and lightly tap with a mallet on the back of the Inserter until the implant is flush to the bone.

Check the final position of EasyFuse implant under fluoroscopy.



Step 8: Additional implants

Repeat steps 2 through 7 for each additional EasyFuse implant used.

Tip: If placing 2 EasyFuse implants in any orientation other than parallel to one another, stagger the implant placement so the legs do not obstruct one another inside the bone.

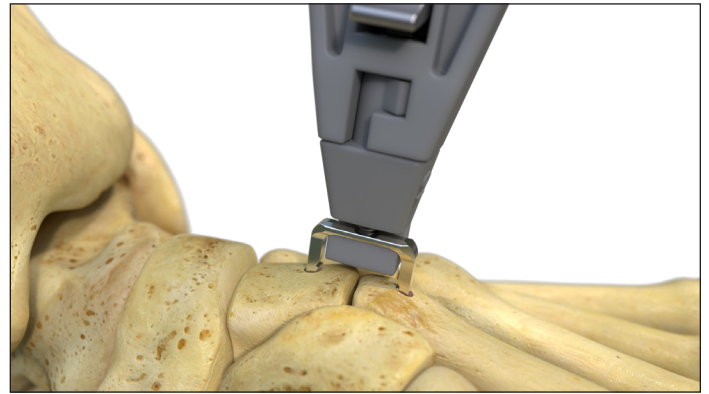


Removal and reinsertion

The EasyFuse implant can be removed using the Universal Implant Inserter and the appropriate implant Cartridge. Assemble the implant Cartridge onto the Universal Inserter. Ensure that the Universal Inserter lever is in its unlocked position.

To remove an EasyFuse implant, use a flat-sided instrument, like an osteotome, to wedge the bridge of the implant slightly off the bone. Place the Cartridge Tip underneath the implant bridge and lock onto the implant by moving the Universal Inserter lever to its locked position. Pull up on the inserter to remove the implant from the bone.

If required, the EasyFuse implant can be repositioned and inserted again following step 5 in the surgical technique.



Explant information

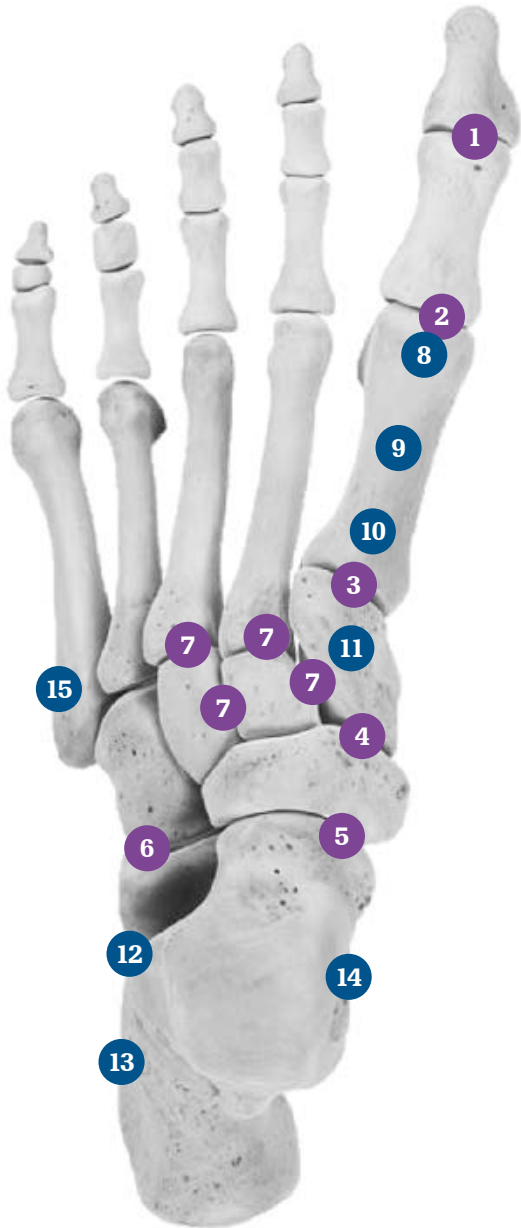
If the removal of the implant is required due to revision or failure of the device, the surgeon should contact the manufacturer using the contact information located on the back cover of this surgical technique to receive instructions for returning the explanted device to the manufacturer for investigation.

Postoperative management

Postoperative care is the responsibility of the treating physician.

Procedural sizing chart

The diagram and chart below highlight some of the suggested procedures and recommended sizing.



Index	Procedure	Implant sizing
1	Hallux IP Fusion	15x12
2	MTPJ Fusion	18x15, 20x15, MTP
3	Lapidus Fusion	15x15, 18x20, 18x25, 20x25 4 Leg
4	Naviculocuneiform Fusion	18x15, 18x20, 20x15, 20x20
5	Talonavicular Fusion	18x20, 18x25, 20x20, 20x25
6	Calcaneocuboid Fusion	18x25, 20x20, 20x25, 4 Leg
7	TMT Fusion	15x15, 15x20, 18x15, 18x20, 20x15, 20x20
8	Chevron Osteotomy	15x15, 15x20, 18x15, 18x20
9	Metatarsal Osteotomy	15x15, 15x20, 18x15, 18x20, 20x15
10	Proximal Base Osteotomy	15x15, 15x20, 18x15, 20x15
11	Cotton Osteotomy	18x15, 18x20, 20x15, 20x20
12	Evans Osteotomy	20x20, 20x25, 25x20, 25x25
13	Calcaneal Osteotomy	20x20, 20x25, 25x20, 25x25
14	Subtalar Fusion	20x20, 20x25, 25x20, 25x25
15	Jones Fracture	15x12, 18x15

Ordering information

2-Leg Implant Part Numbers

Part number	Description
FFS21512	EasyFuse Implant Procedure Pack, 15x12
FFS21515	EasyFuse Implant Procedure Pack, 15x15
FFS21520	EasyFuse Implant Procedure Pack, 15x20
FFS21815	EasyFuse Implant Procedure Pack, 18x15
FFS21820	EasyFuse Implant Procedure Pack, 18x20
FFS21825	EasyFuse Implant Procedure Pack, 18x25
FFS22015	EasyFuse Implant Procedure Pack, 20x15
FFS22020	EasyFuse Implant Procedure Pack, 20x20
FFS22025	EasyFuse Implant Procedure Pack, 20x25
FFS22520	EasyFuse Implant Procedure Pack, 25x20
FFS22525	EasyFuse Implant Procedure Pack, 25x25
FFSP1530	EasyFuse Instrument Procedure Pack

4-Leg Implant Part Numbers

Part number	Description
FFS4MTPS	EasyFuse Implant Procedure Pack, MTP, Small
FFS4MTPL	EasyFuse Implant Procedure Pack, MTP, Large
FFS42520	EasyFuse Implant Procedure Pack, 4-Leg, 25x20
FFS43020	EasyFuse Implant Procedure Pack, 4-Leg, 30x20
FFSP1530	EasyFuse Instrument Procedure Pack

Notes

Notes

Foot & Ankle

This document is intended solely for the use of healthcare professionals. A surgeon must always rely on his or her own professional clinical judgment when deciding whether to use a particular product when treating a particular patient. Stryker does not dispense medical advice and recommends that surgeons be trained in the use of any particular product before using it in surgery.

The information presented is intended to demonstrate a Stryker product. A surgeon must always refer to the package insert, product label and/or instructions for use, including the instructions for cleaning and sterilization (if applicable), before using any Stryker product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your Stryker representative if you have questions about the availability of Stryker products in your area.

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