Trabecular Metal[™] Acetabular Revision System (TMARS)

Cemented Constrained Liner

Surgical Technique

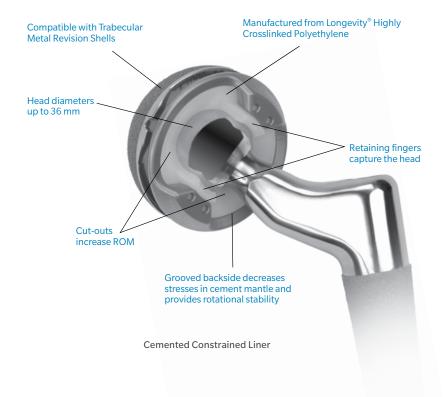




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The Problem

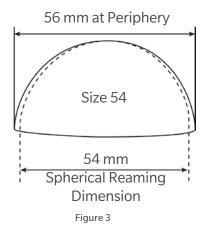


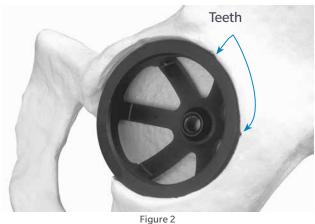
Dislocation is the second most common major complication in THA, occurring after 0.4 - 7% of primary THAs and up to 19% of revision THAs.¹⁻⁴ Dislocation can be physically destructive, leading to abductor tissue damage. Reoperation results in stability in only 69% of cases.⁵

Constrained inserts are designed to reduce the incidence of dislocation. The Cemented Constrained Liner was designed with cut-outs that can be placed where impingement is most likely to occur. For a left hip, the superior finger is placed at 1 o'clock, and for the right hip, it is placed at 11 o'clock.



Figure 1





rigure 2



Figure 4

Prepare the Acetabulum

Use progressively larger reamers to prepare the acetabulum. Hold the reamer steady in the same position in which the shell will be implanted (approximately 45° of abduction and 15° of anteversion) (Figure 1). Minimize the amount of bone reaming, performing only that necessary to achieve creation of an adequate hemispherical cavity for support of the Revision Shell.

Shell Sizing And Positioning

Provisional shell sizes match the outside dimensions of the acetabular reamers. The provisional shell has protruding 1 mm teeth beyond the rim to stabilize it during trial reduction. It also has fenestrations so that shell seating within the acetabulum can be assessed (Figure 2). The elliptical Revision Shell implant provides 2 mm of press-fit at its periphery (Figure 3).

Select the provisional shell that is the same size as the last even-numbered reamer used (the final implant size will match the size of the provisional shell that is used). Screw the Provisional Shell Impactor Handle onto the provisonal shell. Place the T-handled Version Guide into the slot on the Impactor Handle. When the Version Guide is perpendicular to the longitudinal axis of the patient, the provisional shell is properly positioned at 45° of abduction (Figure 4).

Once the version and contact are acceptable, acetabular preparation is complete. Note the position of the provisional shell so that the implant can be seated in the same position.

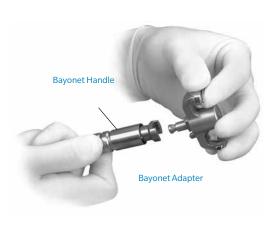


Figure 5a



Figure 5b

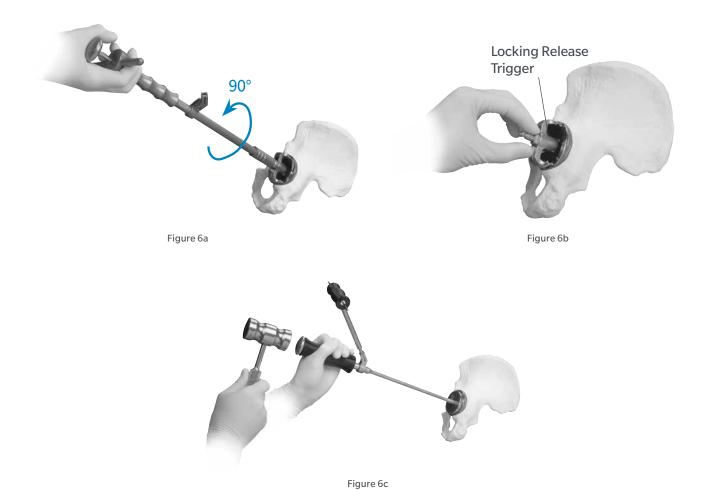


Figure 5c



Instrument Assembly

For shells which have the Bayonet Adapter feature on the rim, assemble the Bayonet Adapter sized to match the implant on the Bayonet Handle (Figure 5a). With the Bayonet Adapter positioned on the flat portion of the rim of the Revision Shell, turn the adapter until it locks into place (Figure 5b). For Jumbo shells, 72-80 mm, which do not have the Bayonet Adapter feature on the rim, utilize the Rim Impactor as shown in (Figure 5c). Place the Version Guide on the Bayonet Handle (Figure 5d). During impaction, the Version Guide should be perpendicular to the longitudinal axis of the patient and parallel to the Transverse axis of the patient.



Implant the Revision Shell

Orient the solid portion of the shell (devoid of screw holes) in an anterior-inferior position. Bring the Revision Shell to the appropriate version and inclination (approx. 45° of abduction and 15° of anteversion). Impact the Bayonet Handle to seat the shell in position.

Note: Ensure that the Plunger is NOT in the Bayonet Handle during impaction.

To release the Bayonet Adapter from the cup, slide the Plunger into the Bayonet Handle. Depress the Plunger until the key lifts out of the slot in the shell, then rotate the Bayonet Handle 90° to free it from the cup locking slot (Figure 6a). Alternatively, the shell can be disengaged by pushing the Locking Release Trigger at the distal end of the Bayonet Adapter, with or without the Bayonet Handle in place (Figure 6b).

For shells which do not have the Bayonet Adapter feature on the rim, the size matched Rim Impactor attached to the Provisional Shell Handle should be used to impact the shell (Figure 6c). For shells which have the Bayonet Adapter feature on the rim, the Rim Impactor can be used for additional impaction following use of the Bayonet Adapter. The Cup Rim Impactor from the General Instrument Set can be used to adjust the face angle of the shell if it is well seated but requires repositioning.

Warning: The Bayonet is for impaction only. Use of this instrument to change the placement of the shell after partial or full seating, or to remove a seated shell, may cause damage to the implant construct. Only direct axial impaction loads should be applied.



Figure 7a



Figure 7b



Figure 7c



Figure 7d

Screw Insertion

Warning: When used with the Cemented Constrained Liner, ancillary screw fixation of the shell is strongly recommended to assist in maintaining fixation at the shell/bone interface until biological fixation can occur.

Drill a pilot hole by placing the drill through the Drill Guide in the desired screw hole (Figure 7a). Measure the hole's depth with the Depth Gauge (Figure 7b).

Attach the Torque Limiter to the Screw-driver (Figure 7c). Avoid overtightening of screws and potential advancement through the shell screw hole.

■ Note: The Torque Limiter does not eliminate the need for surgeon evaluation of bone quality, appropriate screw selection, and torque control. Select the appropriate length 6.5 mm HGPII screw and insert it in the hole with the Screwdriver/Torque Limiter construct (Figure 7d). Place additional screws as necessary.

- Note: Unused screw holes should be plugged with bone wax or bone graft. Bone wax should also be used to fill the screw heads. This may assist bone cement removal if future need arises.
- **Warning:** Avoid screw placement through the shell into the anterior-inferior quadrant of the acetabulum to prevent injury to intrapelvic neurovascular structures.
- Note: The Ring Impactors are sized according to the inner diameter of the insert (28, 32, and 36mm).



Figure 8a Neutral Position - Full Extension.

To optimize Range of Motion, the superior finger is placed at 1 o'clock for a left hip and 11 o'clock on a right hip



Figure 8c Flexion plus internal rotation

Provisional Liner and Trial Reduction

Select a Cemented Constrained provisional liner size that matches the shell. Provisional liners are used to assess joint stability and face-angle position. The purpose of the trial reduction is to locate the optimal rotational position of the constraining fingers to maximize range of motion.

This position may change from patient to patient because of variations in anatomy and shell placement.

For the initial trial range of motion, one of the constraining fingers of the appropriate-sized trial insert is placed at approximately 1 o'clock for a left hip or 11 o'clock for a right hip.

Adjust liner position to best fit the needs of the patient. Perform a trial reduction with the femoral stem and trial femoral head in place.



Figure 8b External rotation in extension



Figure 8d Full flexion

Important: The liner provisional is a direct representation of the assembled implant liner and constraining ring. Therefore, it is extremely important to make sure that all bone and soft tissue has been cleared from the periphery of the shell in order to help facilitate the proper seating of the liner provisional as well as the final implants. This is best accomplished by either direct visualization or by palpating the entire periphery of the shell.



Range of Motion

■ Note: The trial insert is used only to assess leg length and range of motion. It does not constrain the femoral head, as the actual implant does.

A trial femoral head with the appropriate neck length is placed on the trunion of the femoral component and reduced into the trial insert. After the leg length and femoral offset are verified, a trial range of motion is conducted. The key ranges of motion should be assessed (Figures 8a-8d), specifically:

- Maximum flexion in neutral rotation
- Maximum internal rotation with 90° of flexion
- Full extension (but not hyper-extension)
- Full external rotation in full extension

Trial Reduction Range of Motion

If the trial range of motion indicates that the orientation of the constraining fingers does not optimize the range of motion such as might be indicated by premature impingement, the trial insert can be rotated to another position.

■ Note: The Constrained Liner provisional does not lock into the Revision Shell. Rotation may occur during the trial reduction and should be monitored.

Once the optimum orientation of the trial insert is determined, the position of the center of the constraining fingers, shown by an engraved line, is noted on the acetabular shell. This mark will aid in reproducing the location of the constraining fingers with the implant (Figure 9).

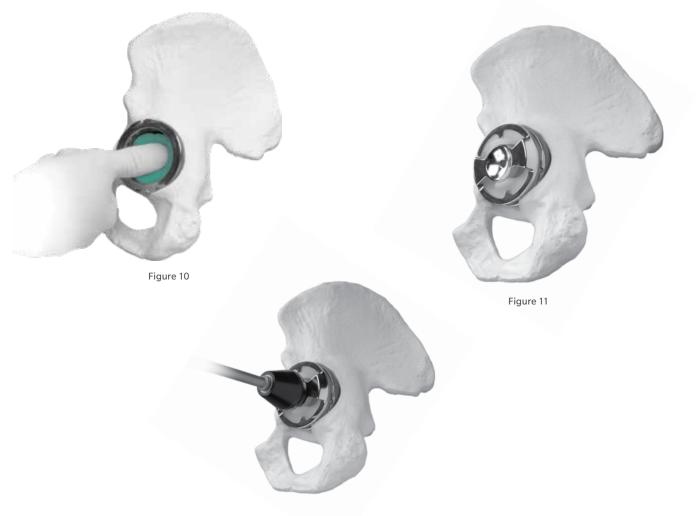


Figure 12

Liner Insertion and Placement

Prepare Bone Cement. Place cement in the Revision Shell while in a doughy state (Figure 10). The Cemented Constrained Liner provides a nominal 2-3 mm cement mantle. If desired, a thicker cement mantle can be achieved by dropping down a liner size (i.e. using a 54 mm OD liner in a 56 mm shell). An appropriately sized Constrained Liner Cement Shroud should be placed on the liner before liner insertion to protect the Constraining Ring locking geometry from being occluded by excess cement (Figure 11). Place the polyethylene liner into position, making sure that the constraining fingers of the Cemented Constrained Liner are aligned in the Revision Shell to replicate the orientation that had provided optimum range of motion during the assessment of the trial insert. The liner insertion may be performed by hand or by use of the Cement Shroud Pusher attached to the Impactor Handle (Figure 12). Maintain pressure on the Cement Shroud while the cement is curing. When the cement is cured, remove the Cement Shroud by lifting the center portion and remove any excess cement.

♠ Note: Care should be taken when removing the Cement Shroud to avoid damage to the articulating surface of the Constrained Liner. If the articulating surface is damaged, the Constrained Liner should not be used.



Figure 13

■ Note: For clarification, the ring is engraved with "TOWARDS FEMUR" and "TOWARDS ACETABULUM" (Figure 14).

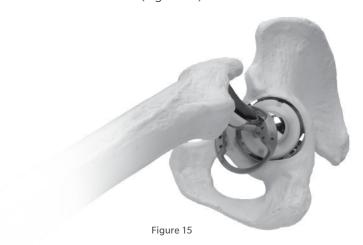








Figure 16

Implant Assembly

Preparation of Constraining Ring

To assemble the Cemented Constrained Liner, place the Constraining Ring over the head of the femoral component in the proper orientation (Figure 13). The top-side of the ring with the two protruding fingers must point toward the femur. The under-side of the ring, which will snap onto the face of the polyethylene liner, must be oriented toward the patient's acetabulum.

Femoral Head Reduction

Note: The constraining ring must be in place around the femoral neck before reducing the head into the liner.

Reduce the appropriately sized femoral head into the Cemented Constrained Liner by applying a continuous, steady force axially along the femur (Figure 15). Attempts should not be made to reduce the femoral head into the insert with a sudden impaction force. Sudden impaction actually requires a higher force to be applied.

Constraining Ring Assembly to Insert

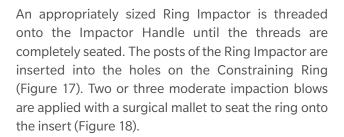
To attach the Constraining Ring to the liner, advance the ring from around the femoral neck to the face of the liner. To ensure proper alignment of the ring, the titanium pegs on the flat side of the constraining ring must fit into the slots on the outside of the polyethylene liner. When properly positioned, the fingers on the ring are aligned with the fingers on the polyethylene liner (Figure 16).



Figure 17



Figure 19



The constraining ring is fully seated when the metal constraining fingers are seated either flush or slightly below the level of the polyethylene constraining fingers on the liner and are at a consistent level



Figure 18

on both sides of the liner (Figure 19). This will be palpable if direct visualization is not possible. If the metal constraining fingers are not seated flush/slightly below the polyethylene on both sides (Figure 20), check that there is no soft tissue trapped between the constraining ring and the periphery of the shell or liner and repeat the impaction with the Ring Impactor.

■ Note: Soft tissue must be cleared from the periphery of the polyethylene insert in order to avoid trapping any soft tissue between the insert and the constraining ring. If difficulty in assembling the ring is encountered, check the periphery for soft tissue impingement.







Figure 21

After assembling the constraining ring to the liner, the range of motion is re-checked and joint stability is verified by applying traction on the femur. If both range of motion and stability are satisfactory, closure of the wound proceeds as usual.

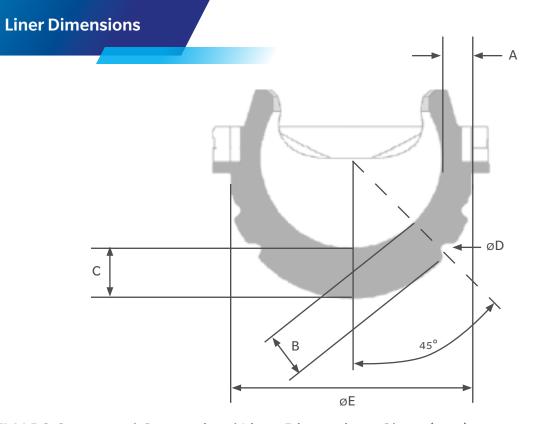
Implant Disassembly (If Required)

To remove the constraining ring, insert a flat instrument, such as a quarter-inch osteotome, under the ring (Figure 21).

Apply rotational torque to the instrument in order to pry the constraining ring from the polyethylene snap feature.

Carefully repeat this process at a few sites around the periphery of the ring until the ring is loosened from the liner.

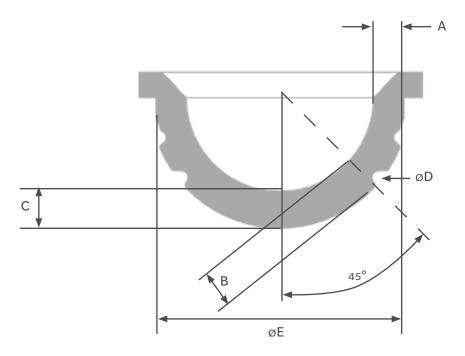
Note: Do not reuse liner or ring if the part has been disassembled. Follow standard liner removal procedure for liner extraction.



TMARS Cemented Constrained Liner Dimensions Chart (mm)

Prod.No	Description	A Rim Thickness	B 45° Thickness	C Pole Thickness	D Outer Diameter	E Rim Diameter	Shell Rim ID
00-7115-050-28	Cemented Constrained Liner 50 x 28	4	8	8	41	38	38
00-7115-052-28	Cemented Constrained Liner 52 x 28	6	9	9	43	40	40
00-7115-054-32	Cemented Constrained Liner 54 x 32	5	7	8	44	42	42
00-7115-056-32	Cemented Constrained Liner 56 x 32	6	9	8	46	45	45
00-7115-058-36	Cemented Constrained Liner 58 x 36	4	7	8	48	46	46
00-7115-060-36	Cemented Constrained Liner 60 x 36	5	8	8	49	48	48
00-7115-062-36	Cemented Constrained Liner 62/64 x 36	7	9	9	51	50	50
00-7115-066-36	Cemented Constrained Liner 66/68/70 x 36	8	11	11	55	54	54
00-7115-072-36	Cemented Constrained Liner 72/74 x 36	10	13	14	60	58	58
00-7115-076-36	Cemented Constrained Liner 76/78/80 x 36	12	15	15	63	62	62

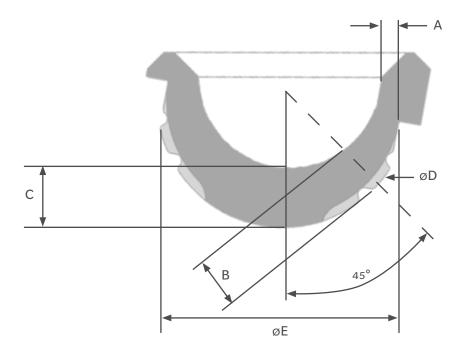
- All dimensions are in millimeters, rounded to the nearest millimeter
- The offset of every Cemented Constrained Liner is 1.8 mm (.072")
- The groove depth is 1.0 mm



TMARS 0 Degree Revision Liner Dimensions Chart (mm)

Prod.No	Description	A Rim Thickness	B 45° Thickness	C Pole Thickness	D Outer Diameter	E Rim Diameter	Shell Rim ID
00-7105-048-28	0° Revision Liner Neutral Face 48 x 28	4.0	4.0	5.5	39.1	37.2	37.6
00-7105-050-28	0° Revision Liner Neutral Face 50 x 28	4.5	4.9	6.4	40.8	38.2	38.5
00-7105-052-28	0° Revision Liner Neutral Face 52 x 28	5.5	5.7	7.2	42.6	40.3	40.7
00-7105-054-28	0° Revision Liner Neutral Face 54 x 28	6.6	6.6	8.1	44.3	42.4	42.8
00-7105-056-28	0° Revision Liner Neutral Face 56 x 28	7.6	7.5	9.0	46.1	44.5	44.9
00-7105-058-28	0° Revision Liner Neutral Face 58 x 28	8.4	8.3	9.8	47.7	46.1	46.4
00-7105-060-28	0° Revision Liner Neutral Face 60 x 28	9.5	9.2	10.7	49.4	48.2	48.5
00-7105-062-28	0° Revision Liner Neutral Face 62/64 x 28	10.5	10.0	11.5	51.1	50.3	50.6
00-7105-066-28	0° Revision Liner Neutral Face 66/68/70 x 28	12.2	11.7	13.2	54.5	53.6	53.9
00-7105-054-32	0° Revision Liner Neutral Face 54 x 32	4.6	4.6	6.1	44.3	42.4	42.8
00-7105-056-32	0° Revision Liner Neutral Face 56 x 32	5.6	5.5	7.0	46.1	44.5	44.9
00-7105-058-32	0° Revision Liner Neutral Face 58 x 32	6.4	6.3	7.8	47.7	46.1	46.4
00-7105-060-32	0° Revision Liner Neutral Face 60 x 32	7.5	7.2	8.7	49.4	48.2	48.5
00-7105-062-32	0° Revision Liner Neutral Face 62/64 x 32	8.5	8.0	9.5	51.1	50.3	50.6
00-7105-066-32	0° Revision Liner Neutral Face 66/68/70 x 32	10.2	9.7	11.2	54.5	53.6	53.9
00-7105-058-36	0° Revision Liner Neutral Face 58 x 36	4.4	4.3	5.8	47.7	46.1	46.4
00-7105-060-36	0° Revision Liner Neutral Face 60 x 36	5.5	5.2	6.7	49.4	48.2	48.5
00-7105-062-36	0° Revision Liner Neutral Face 62/64 x 36	6.5	6.0	7.5	51.1	50.3	50.6
00-7105-066-36	0° Revision Liner Neutral Face 66/68/70 x 36	8.2	7.7	9.2	54.5	53.6	53.9
00-7105-062-40	0° Revision Liner Neutral Face 62/64 x 40	4.5	4.0	5.5	51.1	50.3	50.6
00-7105-066-40	0° Revision Liner Neutral Face 66/68/70 x 40	6.2	5.7	7.2	54.5	53.6	53.9

- All dimensions are in millimeters, rounded to the nearest millimeter
- The offset of every Revision Liner is 1.8 mm (.072")
- The groove depth is 1.0 mm



TMARS 10 Degree Revision Liner Dimensions Chart (mm)

Prod.No	Description	A Rim Thickness	B 45° Thickness	C Pole Thickness	D Outer Diameter	E Rim Diameter	Shell Rim ID
00-7110-048-28	10° Revision Liner Elevated Face 48 x 28	4.5	6.8	9.3	39.1	37.2	37.6
00-7110-050-28	10° Revision Liner Elevated Face 50 x 28	4.5	7.7	10.3	40.8	38.2	38.5
00-7110-052-28	10° Revision Liner Elevated Face 52 x 28	6.1	8.8	11.3	42.6	40.3	40.7
00-7110-054-28	10° Revision Liner Elevated Face 54 x 28	7.2	9.8	12.4	44.3	42.4	42.8
00-7110-056-28	10° Revision Liner Elevated Face 56 x 28	8.4	10.8	13.4	46.1	44.5	44.9
00-7110-058-28	10° Revision Liner Elevated Face 58 x 28	9.2	11.8	14.4	47.7	46.1	46.4
00-7110-060-28	10° Revision Liner Elevated Face 60 x 28	10.3	12.8	15.4	49.4	48.2	48.5
00-7110-062-28	10° Revision Liner Elevated Face 62/64 x 28	11.4	13.9	16.5	51.1	50.3	50.6
00-7110-066-28	10° Revision Liner Elevated Face 66/68/70 x 28	13.2	15.9	18.5	54.5	53.6	53.9
00-7110-054-32	10° Revision Liner Elevated Face 54 x 32	5.2	7.7	10.3	44.3	42.4	42.8
00-7110-056-32	10° Revision Liner Elevated Face 56 x 32	6.3	8.8	11.4	46.1	44.5	44.9
00-7110-058-32	10° Revision Liner Elevated Face 58 x 32	7.1	9.8	12.4	47.7	46.1	46.4
00-7110-060-32	10° Revision Liner Elevated Face 60 x 32	8.2	10.8	13.4	49.4	48.2	48.5
00-7110-062-32	10° Revision Liner Elevated Face 62/64 x 32	9.3	11.8	14.5	51.1	50.3	50.6
00-7110-066-32	10° Revision Liner Elevated Face 66/68/70 x 32	11.1	13.8	16.5	54.5	53.6	53.9
00-7110-058-36	10° Revision Liner Elevated Face 58 x 36	5.0	7.7	10.4	47.7	46.1	46.4
00-7110-060-36	10° Revision Liner Elevated Face 60 x 36	6.1	8.7	11.4	49.4	48.2	48.5
00-7110-062-36	10° Revision Liner Elevated Face 62/64 x 36	7.2	9.7	12.4	51.1	50.3	50.6
00-7110-066-36	10° Revision Liner Elevated Face 66/68/70 x 36	9.0	11.7	14.5	54.5	53.6	53.9
00-7110-062-40	10° Revision Liner Elevated Face 62/64 x 40	5.1	7.7	10.5	51.1	50.3	50.6
00-7110-066-40	10° Revision Liner Elevated Face 66/68/70 x 40	6.9	9.7	12.5	54.5	53.6	53.9

- All dimensions are in millimeters, rounded to the nearest millimeter
- The offset of every Revision Liner is 1.8 mm (.072")
- The groove depth is 1.0 mm

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Notes	

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