Boston Scientific

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CrossBoss™
Catheter

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using a Radiation process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The CrossBoss Catheter facilitates the placement and support of a guidewire into discrete regions of the coronary and peripheral vasculature through its central guidewire lumen. The CrossBoss Catheter contains a rounded distal tip (1 mm diameter) mounted to a flexible and torquable proximal shaft. The CrossBoss Catheter is packaged with a dedicated torque device positioned at its proximal end. The distal end of the catheter is hydrophilic coated. The CrossBoss Catheter is compatible with 6F guide catheters with minimum inner diameter of 0.070 in (1.7 mm), and may be used with guidewires ≤0.014 in (0.36 mm). All components of the CrossBoss Catheter are provided sterile and non-pyrogenic. For dimensional information refer to label.

Contents

Quantity	Material
1	CrossBoss Catheter

INTENDED USE / INDICATIONS FOR USE

The CrossBoss Catheter is intended for use with a guidewire to access discrete regions of the coronary and peripheral vasculature.

When used as part of the system consisting of the CrossBoss Catheter, Stingray™ Catheter, and Stingray Guidewire, the CrossBoss Catheter is indicated for use to facilitate the intraluminal placement of conventional guidewires beyond stenotic coronary lesions (including chronic total occlusions [CTOs]) prior to PTCA or stent intervention.

CONTRAINDICATIONS

- Do not use with guidewire extension systems with a coupling profile larger than 0.014 in (0.36 mm) diameter (i.e. wave pattern coupling mechanism).

WARNINGS

- Only physicians thoroughly trained in interventional procedures should use the CrossBoss Catheter.
- To reduce the potential for vessel damage, the CrossBoss Catheter should only be used in vessels that are ≥1 mm in diameter.
- Always use the included torque device during catheter advancement and manipulation especially during device rotation. Failure to use the included torque device may result in catheter failure and may result in patient injury.

PRECAUTIONS

- Use prior to the Expiration Date.
- In coronary applications, the CrossBoss Catheter should only be used in hospitals where emergency coronary bypass surgery can be immediately performed in the event of a potentially injurious or life threatening complication.
- Before insertion of the CrossBoss Catheter, administer appropriate anticoagulant and vasodilator therapy.
- The CrossBoss Catheter should be handled with care. Prior to use and during the procedure, inspect the packaging and catheter for bends, kinks, or other damage. Discontinue use if the catheter becomes damaged.
- Do not expose to organic solvents.
- The CrossBoss Catheter should only be manipulated under fluoroscopic observation.
- Do not use a syringe smaller than 5 cc (ml) when flushing the catheter.
- Do not use an inflation or power assist device when flushing the catheter.

ADVERSE EVENTS

Potential adverse effects include, but are not limited to, the following:

- Acute myocardial infarction
- Vessel trauma requiring surgical repair or intervention
- Hemorrhage or hematoma
- Artery spasm
- Embolism
- Stroke
- Neurological deficit
- Drug reactions, allergic reaction to contrast media
- Infection
- Recurrence of angina
- Chest discomfort
- Bleeding from the catheter insertion point
- Bruising at the catheter insertion point
- Hematoma at catheter insertion point
- Ischemia due to restenosis of the dilated segment
- Ventricular failure
- Dissection or thrombosis with vessel occlusion
- Arterial Perforation (Surgery required)
- Blood Toxicity
- Toxicological response
- Fever
- Infection at skin puncture site
- Deterioration of kidney function/kidney failure
- Provocation of heart attack/stroke
- Surgery to recover failed devices
- Surgery to repair a failed procedure
- Prolonged procedure time
- Occlusion of a branch of coronary artery
- Myocardial infarction with release of CK-MB into circulation
- Death
- When failures of PTCA occur, they are often treated using coronary artery bypass surgery

HOW SUPPLIED

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Handling and Storage

Store in a cool, dry, dark place.

CLINICAL STUDIES

BridgePoint Medical FAST-CTOs Clinical Trial Observed Adverse Events

The CrossBoss Catheter has been evaluated in the Facilitated Antegrade Steering Technique in Chronic Total Occlusions (FAST-CTOs) Clinical Study for use in the intraluminal placement of conventional guidewires beyond stenotic coronary lesions (including CTOs) prior to PTCA or stent intervention. A total of 147 patients were treated in the study with 140 receiving treatment with the CrossBoss Catheter. Observed serious adverse event rates associated with the procedure are detailed in the following table.

Table 1 – Serious Adverse Events

Adverse Effect	Reported Occurrence
Death	2/147 (1.4%)
Q-Wave MI	0/147 (0.0%)
NQWMI	6/147 (4.1%)
Emergency CABG	0/147 (0.0%)
Target Lesion Revascularization	0/147 (0.0%)
CVA/Stroke	1/147 (0.7%)
Perforation	10/147 (6.8%)
Cardiac Tamponade	0/147 (0.0%)
Pericardial Effusion	3/147 (2.0%)
Arrhythmia Requiring Treatment	5/147 (3.4%)

Clinical Study

The clinical evaluation of the system (comprised of the CrossBoss Catheter, Stingray Catheter, and Stingray Guidewire) in the treatment of patients with stenotic coronary lesions (including CTOs) was performed through the FAST-CTOs Clinical Study. The study was a prospective, non-randomized, multi-center study in which a total of 147 patients were treated. The CrossBoss Catheter was utilized in 140 patients. Treatment of a patient with the system (comprised of the CrossBoss Catheter, Stingray Catheter, and Stingray Guidewire) allowed for the use of any combination of the devices in order to facilitate placement of an intraluminal guidewire into the true vessel lumen distal to the CTO. Typically the CrossBoss Catheter was used to cross the CTO and when needed, the Stingray Catheter and Stingray Guidewire were used to re-enter from the subintimal space.

The primary objectives of the study were to compare the collected data to an established historical control in both the safety (30-day major adverse cardiac events or MACE comprised of death, myocardial infarction, target lesion revascularization, and emergent CABG) and the technical success of the System in CTOs demonstrated to be refractory to conventional guidewire crossing. Secondary endpoints of the study were procedure time and fluoroscopy time.

Eligibility Criteria

Candidates for this study must have met all of the following criteria:

Inclusion Criteria

- be a suitable candidate for non-emergent, coronary angioplasty
- have a documented *de-novo* or restenotic coronary CTO lesion with the following characteristics:
  a) TIMI 0 flow for at least 90 days
  b) refractory to currently marketed guidewire crossing via one of the following:
     i. documentation of a previous failed attempt to cross lesion within the past 12 months; or
     ii. best effort to cross CTO with a guidewire antegrade within 10-15 minutes of fluoroscopy time is unsuccessful; or
     iii. best effort attempt to cross CTO with a guidewire antegrade results in guidewire entering subintimal space
  c) satisfactory distal vessel visualization (collateral supply) with the following characteristics:
     i. distal vessel of at least 1.5 mm in diameter by visual estimation; and
     ii. at least 10 mm of visible distal vessel proximal to any major branch by visual estimation (i.e., potential true lumen re-entry zone in major vessel proximal to the branch)
- have angina or ischemia caused by the occluded artery
- be at least 18 years of age
- have a Body Mass Index (BMI) <40 (weight in kg divided by height in m^2)
- have a left ventricle ejection fraction ≥20%
- sign the Informed Consent Form

Candidates were excluded from the study if any of the following conditions applied:

Exclusion Criteria

- a saphenous vein graft (SVG) CTO or an in-stent CTO
- an aorto-ostial CTO location. (Ostial bifurcation origins may be considered)
- an intolerance to aspirin or a neutropenic response to ticlopidine or clopidogrel
- the appearance of thrombus or intraluminal filling defects
- severe cerebrovascular disease including a history of prior stroke or TIA (within 1 month)
- had a cardiac intervention within two weeks of the procedure
- renal insufficiency (serum creatinine of >2.3 mg/dl)
- active gastrointestinal bleeding
- an active infection or fever (>100° F) that may be due to infection
- a life expectancy <2 years due to other illnesses (e.g., cancer, pulmonary, hepatic or renal disease)
- significant anemia (hemoglobin <8.0 mg / dl)
- severe uncontrolled systemic hypertension (systolic press. >240 mm Hg within the past month)
- a severe electrolyte imbalance
- documented anaphylaxis to angiographic contrast media unless appropriately medicated
- congestive heart failure (NYHA Class IV)
- unstable angina requiring emergent PTCA or CABG
- had a recent MI (within the past two weeks)
- uncontrolled diabetes (>2 serum glucose concentrations of >350 mg/dl within the past 7 days)
- participation in another investigational protocol
- unwillingness or inability to comply with any protocol requirements
- pregnant or nursing
- target vessel with severe tortuosity
- an extensive dissection from refractory guidewire use that may prevent safe intervention or reduce the chance of a successful case
- crossing of the CTO into the true lumen with a currently marketed guidewire within 10-15 minutes of fluoroscopy time
- target true lumen re-entry area with severe calcification defined as readily apparent densities noted within the apparent vascular wall at the site of the stenosis including radio opacities noted without cardiac motion prior to contrast injection generally involving both sides of the arterial wall.

Methods

Patients who met all inclusion criteria and did not meet any exclusion criteria were eligible for inclusion into the FAST-CTOs Study. Once the patient's CTO was demonstrated to be refractory to conventional guidewire crossing, the system (comprised of the CrossBoss™ Catheter, Stingray™ Catheter, and Stingray Guidewire) was used to cross the CTO and/or re-enter from the subintimal space. Upon successful crossing of the CTO and/or re-entry, definitive treatment (typically placement of stents) was performed at the discretion of the investigator. Post-procedure care was according to institutional standard practice with the additional requirement of 3 serial blood draws to test for cardiac enzyme elevation. Patients were required to have an office visit follow-up at 30-days post-procedure.

Results

A total of 150 CTOs were treated in 147 patients. The following table outlines the baseline demographics observed in the FAST-CTOs study.

Parameter	Result
Age	63.3± 9.1
Gender (% Male)	86% (127/147)
Diabetes mellitus (Type I or II)	36% (53/147)
Hyperlipidemia (moderate/severe)	62% (88/143)
Hypertension (moderate/severe)	52% (75/144)
Family history of CAD	37% (52/142)
Tobacco use	19% (28/147)
Prior myocardial infarction	39% (58/147)
Angina pectoris	86% (126/147)
Prior CABG	22% (33/147)
Prior attempt to recanalize CTO	46% (67/147)

The overall technical success for the study was 77% (115/150). This has met the performance goal of 54% The following table summarizes the technical success by refractory category:

Endpoint -by CTO	Overall (n=150)	Failed Prior Procedure (n=61)	10-15 Min. of Fluoroscopy (n=51)	Subintimal Guidewire (n=38)
Technical Success	77% (115/150)	72% (44/61)	73% (37/51)	89% (34/38)

The 30-day MACE rates were calculated for subjects who had follow-up visit within the pre-defined window of -0/+7 days (true completers), and for subjects who had a follow-up visit on or after 30 days or had MACE event before 30 days (completers). The following tables identify the 30-day MACE rate estimates calculated after pooling data over all centers. The 90% confidence interval upper bound was calculated after adjusting for center as random effects.

30-day MACE rate - True Completers (n=102)

MACE Component	Rate Estimate	90% CI upper bound*
MACE	6.9% (7/102)	14.2%
Cardiac Death	2.0% (2/102)	7.1%
Q-wave MI	0.0% (0/102)	---
NQWMI	5.9% (6/102)	12.8%
Target Lesion Revascularization	0.0% (0/102)	---
Emergency CABG	0.0% (0/102)	---

* with center as random effect

30-day MACE rate – Completers (n=136)

MACE Component	Rate Estimate	90% CI upper bound*
MACE	5.1% (7/136)	11.0%
Cardiac Death	1.5% (2/136)	5.5%
Q-wave MI	0.0% (0/136)	---
NQWMI	4.4% (6/136)	9.9%
Target Lesion Revascularization	0.0% (0/136)	---
Emergency CABG	0.0% (0/136)	---

* with center as random effect

The study performance goal for **MACE rate** was 14%.

In addition, the results of the secondary endpoints were 105±54 minutes for procedure time and 44±25 minutes for fluoroscopy time. The performance goals of 146 minutes and 53 minutes were met for procedure time and fluoroscopy time, respectively.

During the course of the FAST-CTOs study, perforations were reported as any observed exit of a device from the vessel lumen including wire exits, myocardial staining, and angiographic (free-flowing) perforation. A perforation was reported in 6.8% (10/147) of the procedures. It was determined by the site investigator and the study Data Safety Monitoring Committee that the system (comprised of the CrossBoss Catheter, Stingray Catheter, and Stingray Guidewire) was involved in half of the events for a perforation rate of 3.4% (5/147). It was determined by the investigator that 4 events were caused by the CrossBoss Catheter located in a small side branch artery and one instance of a Stingray Catheter balloon rupture. The five perforations in which the system (comprised of the CrossBoss Catheter, Stingray Catheter, and Stingray Guidewire) was not involved were caused by a non-study guidewire (n=4/5) and in one case a non-study device-related pericardial effusion was noted post-procedure.

Note: During clinical studies it was noted that use of the system (comprised of the CrossBoss Catheter, Stingray Catheter, and Stingray Guidewire) after extensive attempts to cross CTOs with guidewires (i.e., >20 minutes) led to decreased success of the System.

Conclusions

The FAST-CTOs Study has demonstrated that the CrossBoss Catheter utilized as a component of the system (comprised of the CrossBoss Catheter, Stingray Catheter, and Stingray Guidewire) is safe and effective in the treatment of patients with stenotic coronary lesions (including CTOs) prior to PTCA or stent intervention.

OPERATIONAL INSTRUCTIONS

Supplies

The following supplies are not provided with the device and need to be available and prepped prior to use of the CrossBoss Catheter:

- Guiding catheter
- Angiographic imaging supplies (i.e. radiopaque contrast, manifold, tubing, etc.)
- Sterile heparinized normal saline
- Guidewire
- Other supplies as needed to complete the established laboratory protocol

Product Preparation

1. Remove the CrossBoss Catheter from the sterile packaging.
2. Flush the guidewire lumen with saline.
3. Ensure all device surfaces are exposed to heparanized and sterile saline.
4. Gently tighten the black knob of the CrossBoss Catheter torque device onto the proximal shaft at a position near the proximal hub.

Product Operation – To Access Discrete Regions of the Coronary or Peripheral Vasculature

1. Access the vascular system and place the appropriate size introducer sheath per manufacturer's instructions.
2. Engage the vessel to be treated with an appropriate guiding catheter per manufacturer's instructions. Connect a hemostatic Y-adapter to the guiding catheter hub.

3. Assure the CrossBoss™ Catheter has been prepped per instructions.
4. Remove the appropriate guidewire from its package and inspect for damage.
5. Advance the guidewire to the target location using fluoroscopic guidance.
6. Back-load the CrossBoss Catheter onto the proximal portion of the guidewire.
7. Loosen the knob on the hemostatic Y-adapter.
8. Track the CrossBoss Catheter over the wire and into the proximal guiding catheter lumen.
9. Tighten the hemostatic Y-adapter to create a seal around the CrossBoss Catheter. Do not over-tighten.
10. Advance the CrossBoss Catheter over the guidewire using fluoroscopic guidance.
11. Once the CrossBoss Catheter tip exits the guiding catheter, loosen the black knob on the torque device, slide the torque device to the appropriate position along the proximal shaft and firmly tighten the black knob onto the proximal shaft.
12. While holding the torque device, advance while rotating the CrossBoss Catheter in the clockwise or counterclockwise direction. The CrossBoss Catheter may be advanced over the wire or in front of the wire to the target location.
13. In the event the device encounters significant torsional resistance, the torque device is designed to slip while emitting an audible and tactile "click". Upon torque device slip in one direction, reverse the direction of rotation and continue advancement. Continue clockwise and counterclockwise rotations as needed to advance to the target location.
14. In addition, the CrossBoss Catheter can also be withdrawn slightly and re-advanced in the event of torque device slip.
15. Once the CrossBoss Catheter has been successfully delivered to the target location, advance an appropriate guidewire through the central guidewire lumen of the CrossBoss Catheter.
16. Withdraw the CrossBoss Catheter over the wire and discard. Catheter rotation may also be advantageous during withdrawal.
17. Upon completion of the use of the CrossBoss Catheter, discard according to hospital standards and national legal requirements.

Product Operation – To Treat Stenotic Coronary Lesions (Including CTOs)

Three general scenarios exist where the CrossBoss Catheter, Stingray™ Catheter, and Stingray Guidewires could be used in the treatment of stenotic coronary lesions. The first scenario involves the CrossBoss Catheter crossing the CTO lesion in the vessel true lumen. The second scenario occurs when the initial guidewire used is advanced distal of the CTO but remains in the subintimal space. The Stingray Catheter and Stingray Guidewire are used to re-enter the vessel true lumen. The third scenario occurs when the CrossBoss Catheter crosses the CTO lesion, but remains in the subintimal space. The Stingray Catheter and Stingray Guidewire are then used to re-enter the vessel true lumen.

Scenario 1 – CrossBoss Catheter

1. Access the coronary vascular system and place the appropriate size introducer sheath per manufacturer's instructions.
2. Engage the coronary vessel with the CTO with an appropriate guiding catheter per manufacturer's instructions. Connect a hemostatic Y-adapter to the guiding catheter hub.
3. Remove the appropriate guidewire (physician's choice) from its package and inspect for damage.
4. Advance the guidewire to the target coronary CTO location using fluoroscopic guidance.
5. Assure the CrossBoss Catheter has been prepped per instructions.
6. Back-load the CrossBoss Catheter onto the proximal portion of the guidewire.
7. Loosen the knob on the hemostatic Y-adapter.
8. Track the CrossBoss Catheter over the guidewire and into the proximal guiding catheter lumen.
9. Tighten the hemostatic Y-adapter to create a seal around the CrossBoss Catheter. Do not over-tighten.
10. Advance the CrossBoss Catheter over the guidewire using fluoroscopic guidance.
11. Once the CrossBoss Catheter tip exits the guiding catheter, loosen the black knob on the torque device, slide the torque device to the appropriate position along the proximal shaft and firmly tighten the black knob onto the proximal shaft.
12. While holding the torque device, advance while rotating the CrossBoss Catheter in the clockwise or counterclockwise direction. The CrossBoss Catheter may be advanced over the wire or in front of the wire to the target location.
13. In the event the device encounters significant torsional resistance, the torque device is designed to slip while emitting an audible and tactile "click". Upon torque device slip in one direction, reverse the direction of rotation and continue advancement. Continue clockwise and counterclockwise rotations as needed to advance to the target location.
14. In addition, the CrossBoss Catheter can also be withdrawn slightly and re-advanced in the event of torque device slip.
15. Once the CrossBoss Catheter has been successfully delivered to the target location distal of the CTO, advance an appropriate guidewire through the central guidewire lumen of the CrossBoss Catheter and use fluoroscopic images to confirm that the devices are in the true lumen distal of the CTO.
16. Withdraw the CrossBoss Catheter over the wire and discard. Catheter rotation may also be advantageous during withdrawal.

Scenario 2 — Stingray Catheter and Stingray Guidewire

1. Access the coronary vascular system and place the appropriate size introducer sheath per manufacturer's instructions.
2. Engage the coronary vessel with the CTO with an appropriate guiding catheter per manufacturer's instructions. Connect a hemostatic Y-adapter to the guiding catheter hub.
3. Assure the Stingray Catheter and Stingray Guidewire have been prepped per instructions.
4. Remove the appropriate guidewire (physician's choice) from its package and inspect for damage.
5. Advance the guidewire across the CTO using fluoroscopic guidance. In this scenario the guidewire remains in the subintimal space.
6. Back-load the Stingray Catheter onto the proximal portion of the guidewire.
7. Loosen the knob on the hemostatic Y-adapter.
8. Track the Stingray Catheter over the wire and into the proximal guiding catheter lumen.
9. Tighten the hemostatic Y-adapter to create a seal around the Stingray Catheter. Do not over-tighten.
10. Advance the Stingray Catheter over the guidewire using fluoroscopic guidance. Position the Stingray Catheter ports (using the radiopaque markers) at the target location distal of the CTO.
11. Exchange the guidewire for a Stingray Guidewire.
12. Connect the balloon inflation device to the 3-way stopcock and purge the stopcock with contrast medium mixture.
13. Inflate the balloon to 3-4 atm (304-405 kPa) and confirm inflation via fluoroscopy.
14. Adjust the fluoroscopic view until the balloon is shown at its minimum width and the coronary vessel true lumen direction can be identified.
15. Steer the Stingray Guidewire through the port facing the true lumen by slowly rotating the guidewire immediately proximal of the marker band until the Stingray Guidewire begins to exit the port.
16. Assess proper Stingray Guidewire position and direction.
17. If the Stingray Guidewire position or direction is incorrect, target the other side port by steering the Stingray Guidewire through the desired port by slowly rotating the Stingray Guidewire immediately proximal of the marker band until the Stingray Guidewire begins to exit the port.
18. Advance the Stingray Guidewire through the port to penetrate the intimal tissue for access to the vessel true lumen distal of the CTO.
19. Use fluoroscopic images to confirm that the Stingray Guidewire is in the true lumen distal of the CTO.
20. If a 185 cm Stingray Guidewire was used an extension wire can be attached prior to catheter exchange. Insert the guide pin on the proximal end of the 185 cm Stingray Guidewire into the distal end of the extension wire. Once the guide pin is inserted, rotate the extension wire in a clockwise direction (with respect to the Stingray Guidewire) until the two guidewires are pulled together securely.
21. Check for secure attachment by pulling firmly on both guidewires.
22. Deflate the balloon and withdraw the Stingray Catheter leaving the Stingray Guidewire in place.
23. Advance a balloon catheter or microcatheter over the Stingray Guidewire and exchange for a guidewire of the physician's choice.

Scenario 3 — CrossBoss Catheter, Stingray Catheter and Stingray Guidewire

1. Follow instructions from scenario 1 in steps 1-14.
2. Once the CrossBoss Catheter has been successfully delivered to the target location distal of the CTO, advance an appropriate guidewire through the central guidewire lumen of the CrossBoss Catheter and use fluoroscopic images to confirm that the CrossBoss Catheter is in the subintimal space distal of the CTO.
3. Withdraw the CrossBoss Catheter over the guidewire. Catheter rotation may also be advantageous during withdrawal.
4. Follow instructions from scenario 2 in steps 6-23.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

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EC REP **EU Authorized Representative**

Boston Scientific Limited
Ballybrit Business Park
Galway
IRELAND

AUS **Australian Sponsor Address**

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

Legal Manufacturer

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA
USA Customer Service 888-272-1001

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