

RADIFOCUS<sup>®</sup>

*Glidewire Advantage*<sup>®</sup>

Guidewire

*NaviCross*<sup>®</sup>

Support Catheter

# CLINICAL CASE STUDIES



**PUSHING** BOUNDARIES

**TERUMO**  
INTERVENTIONAL  
SYSTEMS



# Complex Recanalization of Totally Occluded Distal Superficial Femoral Artery

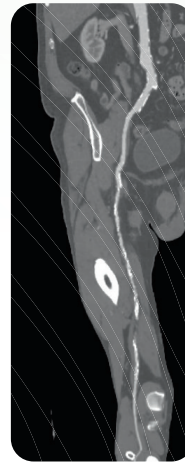
75 YO, MALE

## CLINICAL HISTORY

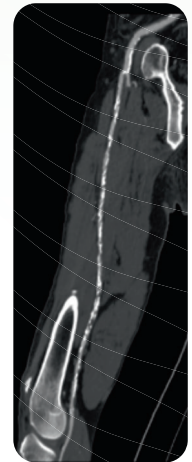
- Type 2 diabetes
- Bilateral cataract operation
- Venous supragenual femoro-popliteal bypass on the left leg (1998)
- Patient admitted due to debilitating intermittent claudication after 500 m in the right leg, no rest pain, no wounds

## BASELINE IMAGING & ANGIO

- CT angiography:
  - Multiple stenotic lesions in the right Superficial Femoral Artery (SFA), total occlusion in the distal right SFA (7 cm, severely calcified)
  - Stenosis at the start of the left femoro-popliteal bypass



CT angio showing total occlusion at distal right SFA



CT angio visualizing a severely calcified right SFA

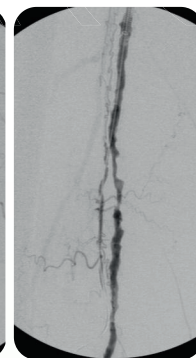
## PROCEDURE

A retrograde puncture of the left femoral artery was performed followed by introduction of 6 Fr introducer sheath with a soft angled guidewire to the aorta. With the use of a modified hook catheter and 0.035" angled Glidewire Advantage, we went over the aortic bifurcation to the right femoral artery.

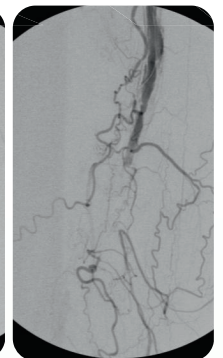
After exchanging the introducer for a 6 Fr Destination guiding sheath (Terumo), an angiogram of the right femoral artery was performed. The first 5 cm of the SFA were diseased, but not stenotic. More distal the SFA was diffusely stenotic combined with a sub-occlusion in the mid part and a total occlusion at the distal SFA. Re-injection occurred at the proximal part of the PA with an open trifurcation below the knee.



Right CFA



Right SFA



Total occlusion of the right SFA with reinjection at the proximal PA

### Right SFA Recanalization

After passing the first stenoses of the SFA, we performed a pre-dilatation of the proximal and mid SFA with 5x12 mm balloon catheter.

No re-entry could be obtained with an antegrade subintimal recanalization.

A retrograde access was obtained by puncture of the right proximal Anterior Tibial Artery (ATA) using the puncture needle with obturator and the short soft 0.035" angled guidewire.

The 0.035" angled Glidewire Advantage was introduced in the PA and the obturator was exchanged for a 90 cm angled NaviCross. With the support of NaviCross, we performed a recanalization of the total occlusion of the proximal PA and distal SFA. After crossing the total occlusion, we performed an angiography through the NaviCross catheter to confirm the intraluminal position. The Glidewire Advantage wire was introduced in the 6 Fr Destination sheath and exteriorized from the introduction site in the left femoral artery.



Angio through the obturator of the needle in the ATA

We performed a pre-dilatation of the total occlusion with 5x120 mm balloon, followed by stenting of the affected mid and distal SFA with 6x150 and 6x120 mm self-expandable stents. Control angiogram showed a smooth contrast flow, with outflow in the 3 distal arteries.

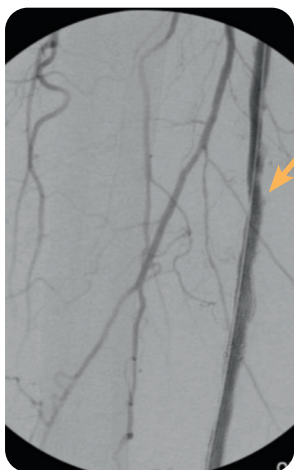
With the use of NaviCross, we exchanged the 0.035" Glidewire Advantage, for a 0.014" angled Glidewire Advantage. The guidewire was introduced in the ATA and 2.5x40 mm balloon was inflated for 5 minutes at the puncture site. Control angiography showed neither contrast leakage nor dissection.

The introducer in the left femoral artery was removed and we performed manual compression for 20 minutes and a compression bandage was placed.



Angio after pre-dilatation of the PA and distal SFA

## FINAL ANGIO & OUTCOME



Post-stenting angio of the mid and distal SFA (arrow at previously total occluded segment)



Angio of PA and trifurcation after removal of NaviCross

## CONCLUSION

- Glidewire Advantage is my preferred guidewire to cross the aortic bifurcation due to the atraumatic tip and stiff shaft. With Glidewire Advantage, it is not necessary to exchange a stiff wire for a soft wire once crossover access is obtained. Furthermore the steerability of this wire is excellent, which is important when working in a crossover position, especially when we want to pass a total occlusion. Since the tip is soft and atraumatic, 0.035" Glidewire Advantage is also suitable for proximal tibial artery access. In combination with the low profile of NaviCross support catheter, a sheathless retrograde procedure is possible resulting in a smaller puncture hole in the punctured vessel.
- The combination of the steerable Glidewire Advantage with the support of NaviCross is ideal for retrograde recanalization of total occlusions of the femoro-popliteal artery.





# Popliteal Occlusion in Patient With Recent Aorto-Bifemoral Bypass

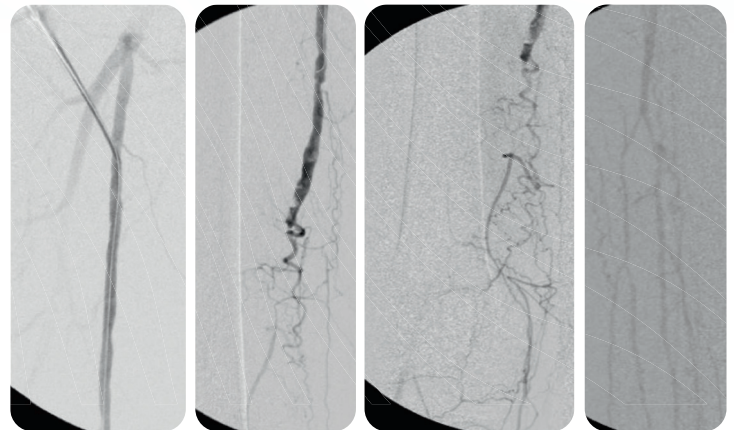
64 YO, MALE

## CLINICAL HISTORY

- Former smoker
- Type 2 diabetes, arterial hypertension, dyslipidemia
- Ilio-femoral bypass with PTFE + venous (Great Saphenous Vein - GSV) femoropopliteal (P1) bypass in the left lower limb due to critical limb ischemia (2008)
- Transmetatarsal amputation of the left foot (2010)
- Aorto-bifemoral bypass due to abdominal aortic aneurysm (2017)
- Currently, the patient presents an ulcer at the first metatarsal head of the right foot

## BASELINE IMAGING & ANGIO

- Right lower limb Duplex Ultrasound:
  - Occlusion of the Popliteal Artery (PA) (P1 & P2)
- Angiogram:
  - Occlusion of the PA (P1 & P2) and of the Posterior Tibial Artery (PTA)



Baseline angio showing the occlusion of the PA (P1 & P2) and PTA

## PROCEDURE

We performed an antegrade approach by US guided puncture in the first centimeters of the Superficial Femoral Artery (SFA) in the right groin introducing a 10 cm 6 Fr Terumo sheath and performed an angio that showed the occlusion of the PA (P1 & P2) and PTA.

### PA and PTA Recanalization

The antegrade recanalization of the PA was unsuccessful using different 0.018" wires, CTO wires and NaviCross. We then tried to recanalize the occlusion by a subintimal approach with no success.

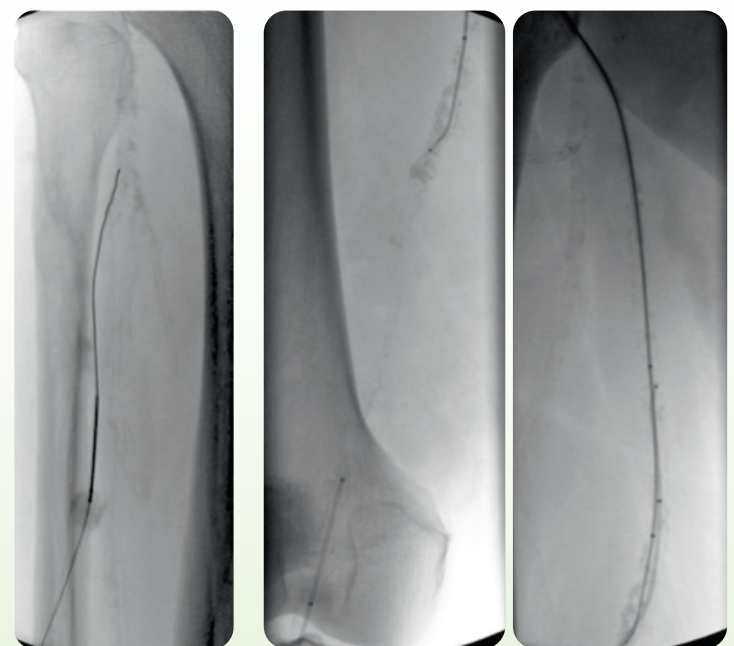
We decided to perform a retrograde puncture of the Anterior Tibial Artery (ATA) using a sheathless technique. We tried to recanalize the lesion from below using a V-18 wire and a 0.018" CXI catheter but we did not succeed again.

Finally, we chose the combination of a 0.035" Glidewire Advantage and NaviCross catheter to obtain a very good support and create a subintimal channel from the retrograde approach, overcoming the occlusion and re-entering the true lumen from this way. After that, we exchanged the 0.035" Glidewire Advantage for a 0.018" Advantage that was externalized through the proximal NaviCross to continue the procedure from the antegrade approach.

We pre-dilated the occlusion with 5x150 mm Crosstella OTW balloon (Terumo) and placed a 6x250 mm endoprosthesis accomplishing a good result after post-dilating with 6x200 mm Crosstella OTW balloon (Terumo). Due to a residual stenosis distally to the endoprosthesis, a 5x100 mm stent was placed overlapping it.

The puncture site at the SFA was closed with 6 Fr Angio-Seal Evolution (Terumo) and the retrograde access was manually compressed for 5 minutes.

Finally, the head of the first metatarsal was resected through the ulcer of the patient.



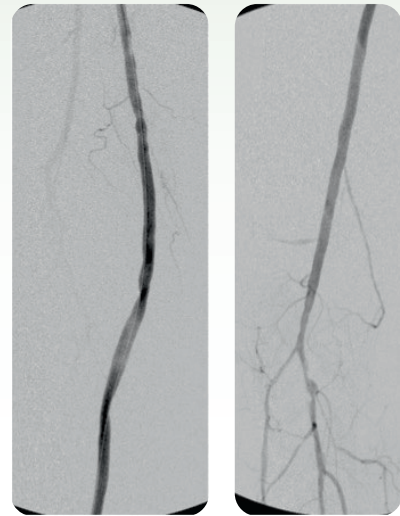
Retrograde puncture of the ATA

Two NaviCross support catheters, one coming from the antegrade approach and the other from the retrograde access



## FINAL ANGIO & OUTCOME

- Patency of the femoro-popliteal segment even when the patient bended his knee
- No defects or lesions at the level of the retrograde puncture site
- 8 months later:
  - The patient is asymptomatic with pedal pulse
  - His ulcer healed quickly and currently he has no walking distance limitations
  - No stenosis or occlusion were detected by US
- The patient is under Clopidogrel and Aspirin treatment



*Final femoro-popliteal angio with the knee extended*



*Final popliteal angio with the knee bent showing no defects nor lesions at the retrograde puncture site (arrow)*

## CONCLUSION

- The combination of NaviCross support catheter and Glidewire Advantage is useful in facing the most complex occlusions especially when we perform a retrograde access and we need a lot of support and to be aggressive to overcome the occlusion, like this case.
- NaviCross provides high pushability, great crossability, excellent navigation and very good torqueability, with its low profile and tapered tip. Glidewire Advantage combines great durability, excellent navigation, torque control and extra support. This combination creates a powerful win-win situation to reach and cross any lesion.



# Highly Calcified Popliteal and BTK Vessels Occlusion in Patient with Previous Bilateral Venous Femoro-popliteal Bypass

74 YO, MALE

## CLINICAL HISTORY

- Former smoker
- Type 2 diabetes, arterial hypertension, dyslipidemia
- Coronary artery disease (CABG, 2008), atrial fibrillation
- Chronic renal insufficiency
- Venous (Great Saphenous Vein - GSV) femoro-popliteal (P1) bypass in the right lower limb (2005) rescued by endovascular treatment once
- Venous (GSV) femoro-popliteal (P1) bypass in the left lower limb (2009)
- Currently, the patient suffers from ischemic rest pain in the left foot

## BASELINE IMAGING & ANGIO

- Left lower limb Duplex Ultrasound:
  - Patency of the venous femoro-popliteal bypass
  - Occlusion of the popliteal segments (P2 & P3) and below-the-knees (BTK) vessels
- Left lower limb Angiogram
  - Patency of the venous femoro-popliteal (P1) bypass
  - Highly calcified popliteal (P2 & P3) occlusion
  - Occlusion of BTK vessels in their full length, no patent artery in the foot

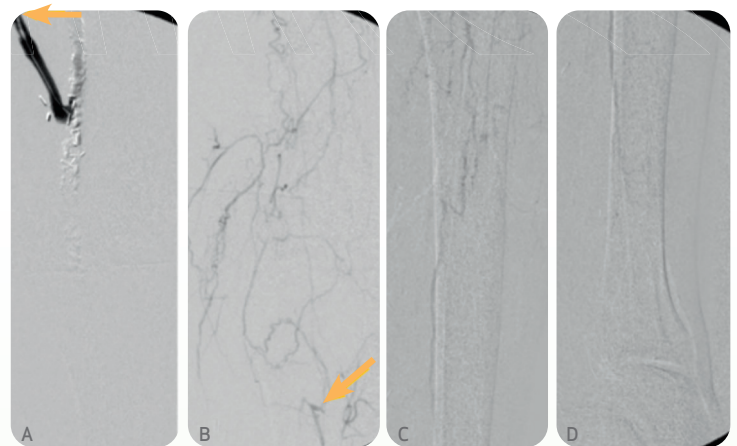
## PROCEDURE

We performed an antegrade approach by a US guided puncture of the bypass in the left groin introducing a 55 cm 6 Fr sheath in the bypass proximal to the distal anastomosis. We performed a second US guided puncture in the Common Femoral Artery (CFA) of the same groin and placed a 10cm 5 Fr Terumo sheath in the profunda to be able to identify the Anterior Tibial Artery (ATA) ostium.

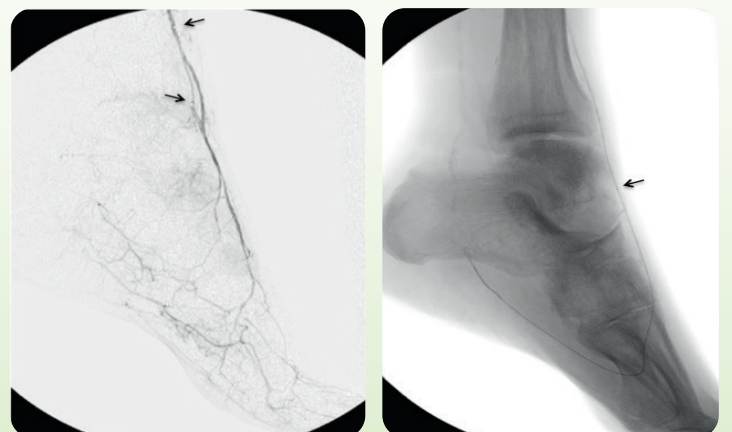
We recanalized the Popliteal Artery (PA) and the ATA by a planned subintimal approach using NaviCross support catheter and 0.018" Glidewire Advantage through the first sheath.

We pre-dilated and treated the ATA with respectively 2x120 and 3x200 mm Crosstella OTW balloons (Terumo). Next, the PA and the ATA arch were prepared with 6x80 mm Crosstella OTW balloon (Terumo) to place two interwoven nitinol stents of 4x60 and 5x200 mm from the ATA arch to the distal segment of the bypass. Several flow limiting dissections were observed in the ATA: the dissections were treated with 3x150 and 3x120 mm drug coated balloons and with 4x170 and 4x100 mm self-expanding stents.

Punctures closure was performed with two 6 Fr Angio-Seal Evolution (Terumo).



Baseline angio in the left groin showing:  
**A.** the patency of the venous femoro-popliteal (P1) bypass with a highly calcified popliteal (P2 & P3) occlusion. **B.** the ostium of the anterior tibial artery. **C.** The occlusion of the BTK vessels in their full length. **D.** No patency in the foot.

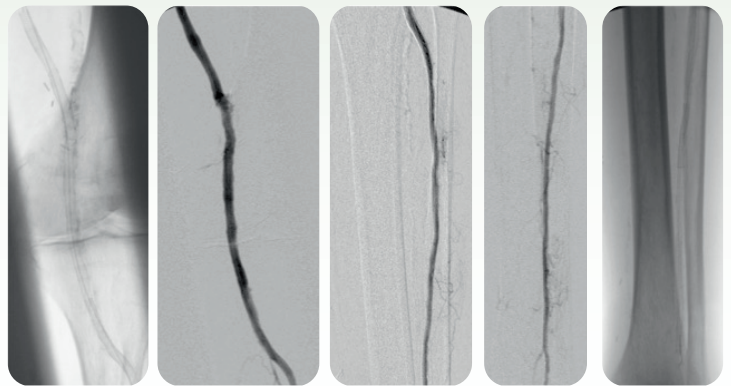


Angio through NaviCross after recanalization of the PA and ATA showing the foot vessels

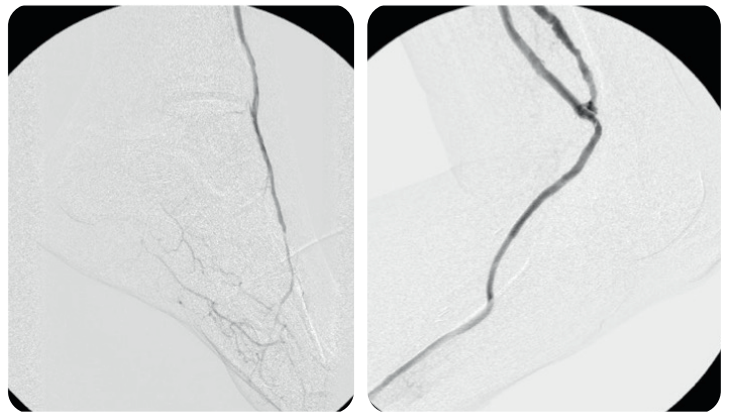
Glidewire Advantage in the plantar loop

## FINAL ANGIO & OUTCOME

- Patency of the femoro-popliteal segment, the ATA and foot vessels
- No residual stenosis, recoil or flow limiting dissections even when the patient bended his knee
- 8 months later
  - The patient is asymptomatic with pedal pulse
  - His walking capacity is not limited
  - No stenosis nor occlusion were detected by US
- The patient took Heparin, Aspirin and Clopidogrel for 6 months. Currently, he is under Clopidogrel and Acenocumarol treatment for life.



*Final angio of the PA and ATA showing good results*



*Final angio of the foot vessels*

*Final angio of the PA with the knee flexed*

## CONCLUSION

The combination of NaviCross support catheter and Glidewire Advantage is useful in facing the most complex occlusions. NaviCross provides high pushability, great crossability, excellent navigation and very good torqueability, with its low profile and tapered tip. Glidewire Advantage combines great durability, excellent navigation, torque control and extra support. This combination creates a powerful win-win situation to reach and cross any lesion.



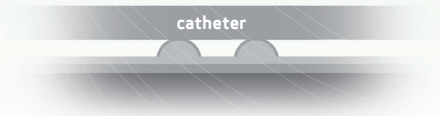
RADIFOCUS®

# Glidewire Advantage®

Guidewire

## IMPROVED PLATFORM FOR INTERVENTIONAL DEVICES\*

- Extra stiff proximal Nitinol shaft provides additional device support\*
- Proximal spiral PTFE coating limits surface contact within catheter lumen, reducing friction and improving trackability over the guidewire\*



## IMPROVED CROSSABILITY\*

More pushability and kink resistance with extra stiff proximal Nitinol shaft\*, even in complex lesions



## SUPERIOR TACTILE FEEDBACK\*

Unique proximal spiral-cut PTFE structure enables a firm grip on guidewire shaft for steerability and comfortable handling

## BEST IN CLASS TRACKABILITY

Distal 25 cm of the original Radifocus® Guide Wire M gives you the M Coat™ performance you trust

## ORDERING INFORMATION

Product code	Wire type	Outer diameter	Overall length	Distal hydrophilic coated length	Flexible tip length	Tip shape
RA*FA14181CM	Extra stiff	0.014"/0.36 mm	180 cm	25 cm	1 cm	Angled 
RA*FA14301CM	Extra stiff	0.014"/0.36 mm	300 cm	25 cm	1 cm	
RA*FA18181CM	Extra stiff	0.018"/0.46 mm	180 cm	25 cm	1 cm	
RA*FA18301CM	Extra stiff	0.018"/0.46 mm	300 cm	25 cm	1 cm	
RA*CA35185CM	Extra stiff	0.035"/0.89 mm	180 cm	25 cm	5 cm	
RA*CA35265CM	Extra stiff	0.035"/0.89 mm	260 cm	25 cm	5 cm	
RA*FS14301CM	Extra stiff	0.014"/0.36 mm	300 cm	25 cm	1 cm	Straight 
RA*FS18301CM	Extra stiff	0.018"/0.46 mm	300 cm	25 cm	1 cm	
RA*CS35185CM	Extra stiff	0.035"/0.89 mm	180 cm	25 cm	5 cm	
RA*CS35265CM	Extra stiff	0.035"/0.89 mm	260 cm	25 cm	5 cm	

\* Compared to Radifocus® Guide Wire M.

# NaviCross®

Support Catheter

## Stainless Steel Double-Braiding

Highly kink-resistant with great torque control and optimal push transition from proximal shaft to distal tip

## Small Crossing Profile

Provides seamless guidewire-to-catheter transition leading to high support and successful lesion crossing

## Hydrophilic M Coat™ 40 cm Distally

Ensures Best-in-Class trackability in challenging anatomy and great crossability of complex lesions

## Three Radiopaque Markers

Facilitates accurate assessment of position and intraluminal measurement of stent and balloon sizes



## PRODUCT SPECIFICATIONS

**Braiding:** Double-braided stainless steel

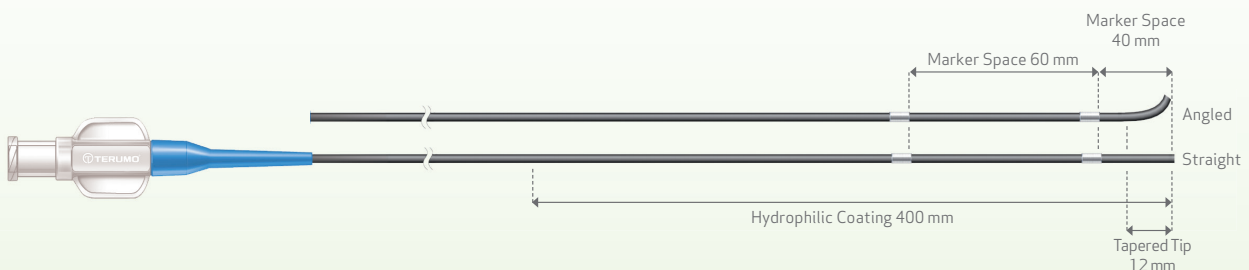
**Wire compatibility:** 0.035"

**Outer diameter:** 4 Fr

**Lengths:** 65, 90, 135, 150 cm

**3 Radiopaque markers:** 1 mm from tip – 40 mm and 60 mm from precedent marker

**Tip:** Straight and 30° Angled



## ORDERING INFORMATION

	0.035" / 0.89 mm Wire compatibility	65 cm	90 cm	135 cm	150 cm
Tip shape	Straight	WS*NS350G3HM	WS*NS35093HM	WS*NS350N3HM	WS*NS35153HM
	Angled	WS*NA350G3HM	WS*NA35093HM	WS*NA350N3HM	WS*NA35153HM



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