



ROTAPRO™
Rotational Atherectomy System

Value Brochure

For ROTAPRO with OS 2.0

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PRODUCT OVERVIEW

WHAT IS ROTATIONAL ATHERECTOMY?

A catheter-based interventional cardiology procedure which utilizes a high-speed rotational device to ablate atherosclerotic plaque and calcium, restore luminal patency, and prepare the vessel for stenting.

WHAT MAKES THE **ROTAPRO** ROTATIONAL ATHERECTOMY SYSTEM UNIQUE?

ROTAPRO Rotational Atherectomy System is the only device to combine the gold standard rotational atherectomy with an easy-to-use platform and is designed to reduce both setup and procedural time.



TECHNOLOGY OVERVIEW

ROTAPRO Rotational Atherectomy System delivers reliable performance with gold standard rotational atherectomy on an easy-to-use platform.

- Produces precise and predictable results
- Over 30 years of proven clinical safety and efficacy

Console

- Vibrant Digital Display – Enhanced feedback and deceleration indicator
- Streamlined Connections – Quick and easy setup
- IV Pole Clamp – Installation flexibility

Advancer

- Easy-to-use Controls – Incorporated on the advancer
- Ergonomic Dynaglide™ Design – Simple system removal
- Hybrid Harness – Improved cable management



GENERAL SPECIFICATIONS

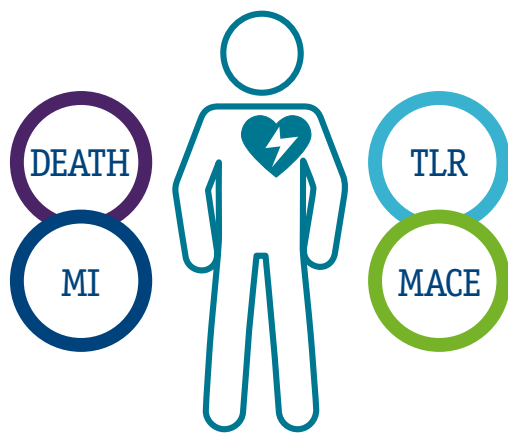
ROTAPRO Rotational Atherectomy System

Indication	<p>Percutaneous rotational coronary atherectomy with the ROTAPRO Rotational Atherectomy System, as sole therapy or with adjunctive percutaneous coronary intervention (PCI) is indicated in patients with calcific coronary artery disease who meet one of the following selection criteria:</p> <ul style="list-style-type: none">• Single vessel atherosclerotic coronary artery disease with a stenosis that can be passed with a guidewire;• Multiple vessel coronary artery disease that in the physician's judgement does not pose undue risk to the patient;• Patients who have had prior PCI, and who have native coronary artery post-balloon angioplasty restenosis; or,• Native vessel atherosclerotic coronary artery disease that is less than 25 mm in length.
Mechanism of Action	<p>Front cutting burr that rotates concentrically over a guidewire and differentially ablates plaque and calcium to optimally prepare the vessel prior to stenting</p>
System Components	<p>ROTAPRO™ System Console, ROTAPRO™ Pre-Connected Exchangeable Burr Catheter and Burr Advancing Device, ROTAWIRE™ Guide Wire</p>

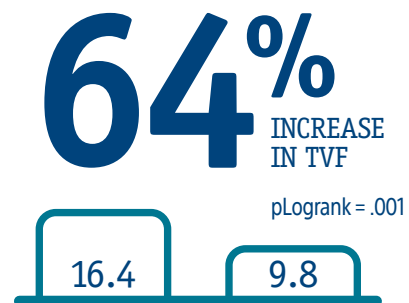
CORONARY CALCIUM PREVALENCE

Calcium is a Predictor of Worse Outcomes

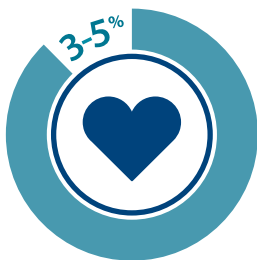
Calcium is being severely undertreated. Calcium can also have a major impact on long-term outcomes.



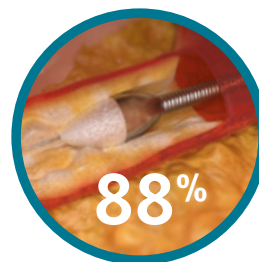
Moderate to severe calcification in the coronary artery is associated with **increased rates** of MACE and death¹.



TVF is higher in patients with severe calcification. At two years, TVF was **16.4%** for those with severe calcification vs **9.8%** for those without severe calcification^{2,3}.



Atherectomy is only used in **3-5%** of PCI cases⁴.



An estimated **88%** of identified calcium is left untreated⁴.

¹ Généreux, P. et al. *J Am Coll Cardiol* 2014 May;63(18):1845-1854.

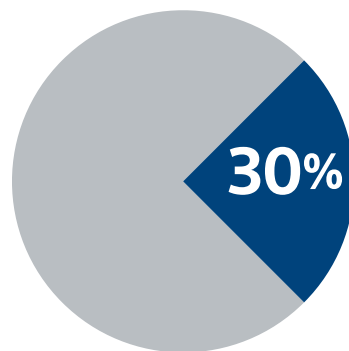
² Adapted from Kirtane, CHIP DC 2017; Huisman et al. *Am Heart J* 2016.

³ Impact of Severe Lesion Calcification on Clinical Outcome of Patients With Stable Angina, Treated With Newer Generation Permanent Polymer-Coated Drug-Eluting Stents: A Patient-Level Pooled Analysis From TWENTE and DUTCH PEERS (TWENTE II) - doi: 10.1016/j.ahj.2016.02.012.

⁴ Based on BSC led survey of HPCs.

CORONARY CALCIUM PREVALENCE

Use of the **ROTAPRO** Rotational Atherectomy System is essential to adequately prepare calcified vessels for stenting.¹⁻³ If left untreated, calcium can lead to stent underexpansion and malaposition⁶⁻⁹, which has been shown to increase target lesion revascularization and stent thrombosis and hospital readmission rates.^{4,5} **ROTAPRO** can help optimize calcium treatment.¹⁻³



30% of all PCIs contain moderate to severe calcium.*

31%

**Increase
1999 – 2011**

This represents a **31%** increase over the last two decades alone.*

Patient Risk Factors

SMOKING
DIABETES
PREVIOUS CABG
AGE
HYPERTENSION
RENAL FAILURE
CONGESTIVE HEARTFAILURE

*As reported to NHLBI Dynamic Registry. Bortnick AE et al. *Am J Cardiol.* 2014;113(4):573-9.

¹ Couper, LT et al. *Catheter Cardiovasc Interv* 2015;86(4):626-31.

² Kawamoto, H et al. *Catheter Cardiovasc Interv* 2016;88(6):881-889.

³ Mohamed, AW. et al. *Circulation: Cardio. Int.* 2018 Sep 24.; 11:e007415.

⁴ Abdel-Wahab, et al. *JACC Cardiovasc Interv.* 2013 Jan;6(1):10-9.

⁵ Carrié, D., *EuroPCR* 2019.

⁶ Moussa I, et al. *Circulation.* 1997;96(1):128-136.

⁷ Mosseri M, et al. *Cardiovasc Revasc Med.* 2005;6:147-53.

⁸ Vavarunakis et al. *Catheter Cardiovasc Interv* 2001;52:164-172.

⁹ Hoffmann et al. *Eur Heart J* 1998;19:1224-31.

ORDERING INFORMATION

ROTAPRO™ Rotational Atherectomy System Ordering Information

Model/Description	GTIN	Ref/Catalog Number
ROTAPRO System Console		
ROTAPRO Console Kit	08714729975151	H749 3930903 0
ROTAPRO Pre-Connected Burr and Advancing Device		
1.25 mm	08714729893356	H749 39300125 0
1.50 mm	08714729893363	H749 39300150 0
1.75 mm	08714729893370	H749 39300175 0
2.00 mm	08714729893387	H749 39300200 0
2.15 mm	08714729893394	H749 39300215 0
2.25 mm	08714729893400	H749 39300225 0
2.38 mm	08714729893417	H749 39300238 0
2.50 mm	08714729893424	H749 39300250 0
ROTAWIRE™ Guidewire		
ROTAWIRE Floppy Guidewire with WireClip Torquer	08714729195566	H802 22824002 2
ROTAWIRE Extra Support Guidewire with WireClip Torquer	08714729195573	H802 23239001 2
ROTALINK™ Exchangeable Burr Catheter		
1.25 mm	08714729185864	H802 22768002 0
1.50 mm	08714729185857	H802 22768003 0
1.75 mm	08714729185840	H802 22768004 0
2.00 mm	08714729126881	H802 22768005 0
2.25 mm	08714729185819	H802 22768006 0
2.50 mm	08714729185796	H802 22768007 0
2.15 mm	08714729185826	H802 22768015 0
2.38 mm	08714729185802	H802 22768016 0
Accessories		
ROTAGO™ Cart	08714729974307	H749 3936901 0
Power Cord, Type E/F	08714729975366	H749 3936803 0
Power Cord, Type G	08714729975465	H749 3936813 0
Power Cord, Type H	08714729975434	H749 3936810 0
Power Cord, Type J	08714729975380	H749 3936805 0
Power Cord, Type K	08714729975410	H749 3936808 0
ROTAPRO Gas Hose, Braided, Clear 20'	N/A	H749 3937301 0
WireClip Torquer – Box of 5	08714729195535	H802 22196003 2

ORDERING INFORMATION

Manufacturer	Boston Scientific
Manufacturer federal tax ID	04 269 5240
Will this product replace or supplement a current in-house product?	This product can replace existing ROTABLATOR™ Rotational Atherectomy System and replace and/or supplement alternative coronary atherectomy devices.
Ship unit	1 ROTA PRO ROTALINK™ Pre-Connected Advancer/Burr contains 1 unit. 1 box of ROTAWIRE™ contains 5 units.
Minimum order quantity?	No
What is the list price per each unit or unit of utilization?	Please speak to your Boston Scientific sales representative for pricing.
Method of purchase	Please speak to your Boston Scientific sales representative regarding sales programs for this purchase.
Workstation storage considerations	Per the DFU, store in a cool, dry, dark place.
Is this a dated product?	Yes, disposable components have a 2-year shelf life.
What department(s) will use and/or be affected by this product?	Operating Room, Cardiology Suite, and Purchasing.
Will there be additional implementation costs, such as installation, cost of education, impact on equipment or additional space?	Wet heart training and 3 proctored cases by a BSC sales representative is suggested prior to use. Compressed gas supply is required per the guidelines of the DFU. Minimal storage of capital system components is required when not in use.
Will this product require evaluation by any of the following departments?	Epidemiology/Infection Control? No Safety and Security? No Bio Engineering Maintenance? Yes Pathology/Labs? No
Does this item and its packaging contain latex?	There is no detectable latex in this product.



Discover Unprecedented Value in the Cath Lab

Partnering with companies who just offer products is no longer adequate. You need a partnership that goes beyond the product on the shelf to address your most critical business concerns. Whether you're looking to improve patient experience, manage high-risk admission costs, attract and retain top talent, standardize care protocols, or simply increase productivity and utilization, Boston Scientific can be your strategic partner for all things PCI.

Caution: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.
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