Medtronic News

Medtronic Receives CE Mark Approval for Radial Artery Access Portfolio

- Portfolio Features First Catheter Specifically Designed to Allow Neurointerventionalists Radial Artery Access, Delivers Advantages to Patients Treated for Stroke, Brain Aneurysms, Other Neurovascular Conditions
- Now Available in the United Kingdom, Italy, Spain, Germany and France

DUBLIN, Sept. 28, 2021 /PRNewswire/ -- Medtronic plc (NYSE:MDT), the global leader in medical technology, today announced it has received CE Mark approval for its radial artery access portfolio, which includes the Rist™ 079 Radial Access Guide Catheter and Rist™ Radial Access Selective Catheter.

The Rist 079 Radial Access Guide Catheter is the first catheter specifically designed for the unique demands of accessing the neuro vasculature through the radial artery versus access through the transfemoral artery. 510(K) cleared by United States Food and Drug Administration[1], the product has been in use at limited sites in the U.S. and received strong customer feedback in over 100 cases on its outperformance in navigability and support for the radial pathway.

"With excellent navigability, this first-of-its-kind device will allow clinicians to reach distal locations while still achieving excellent stability to the system," said Dr. Alejandro Tomasello, head of Interventional Neuroradiology Unit at Vall d'Hebron Hospital, Barcelona, Spain. "The radial artery-access portfolio works well in tandem with Phenom™ PLUS, Phenom™ 021 microcatheter for stent deployment or Phenom™ 027 microcatheter for flow diverter deployment, which is a fantastic set up for Pipeline™ VANTAGE Embolization Device with Shield Technology™ treatments."

Transradial techniques are now the standard of care in the cardiac interventional community since the American Heart Association recommended a radial-first approach for acute coronary syndrome in 2018 citing lower bleeding and vascular complications than transfemoral artery access[2,3]. Other advantages demonstrated in cardiovascular procedures to radial access include strong patient preference[4], immediate ambulation and reduced costs[5,6], which have led the neuro-interventionalist community to examine adoption of the transradial approach to their practice.

"We are committed to exploring ways to improve outcomes through complication reduction, reducing the cost of care and improving the overall patient experience. We believe radial access is a meaningful addition to the clinical armamentarium," said Dan Volz, president of the Neurovascular Therapies business, which is part of the Neuroscience Portfolio at Medtronic. "The CE Mark approval of the Rist radial access portfolio emphasizes our focus on driving innovation that gives clinicians who perform neurovascular procedures the broadest product portfolio so they can customize their care based on a patient's condition and anatomy."

About the Rist™ Radial Access Catheters

The Rist 079 Radial Access Guide Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

The Rist Radial Access Selective Catheter is indicated for the introduction of interventional devices into the peripheral, coronary and neuro vasculature. It can be used to facilitate introduction of diagnostic agents in the neuro vasculature. It is not intended to facilitate introduction of diagnostic agents in coronary or peripheral arteries.

About Medtronic

Medtronic plc (www.medtronic.com), headquartered in Dublin, Ireland, is among the world's largest medical technology, services and solutions companies – alleviating pain, restoring health and extending life for millions of people around the world. Medtronic employs more than 90,000 people worldwide, serving physicians, hospitals and patients in more than 150 countries.

The company is focused on collaborating with stakeholders around the world to take healthcare Further, Together.

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.

1. Rist Neurovascular Inc. 510(k) K191551 and K201682
2. Mason, Peter, et al. JACC Cardiovasc Interv. 2018, 11.
3. Ferrante G, et al. JACC Cardiovasc Interv. 2017;9(14):1419-1434.
4. Amin AP, et al. JACC Cardiovasc Interv. 2013;6(8):827-834.
5. Cooper CJ, et al. Am Heart J. 1999;138(3):430-436.
6. Amaroso G, et al. Eur J Cardiovasc Nurs. 2006;5(1):3-4.

See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.com.

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