Medtronic

Artisse™ Intrasaccular device

Strength in conformability

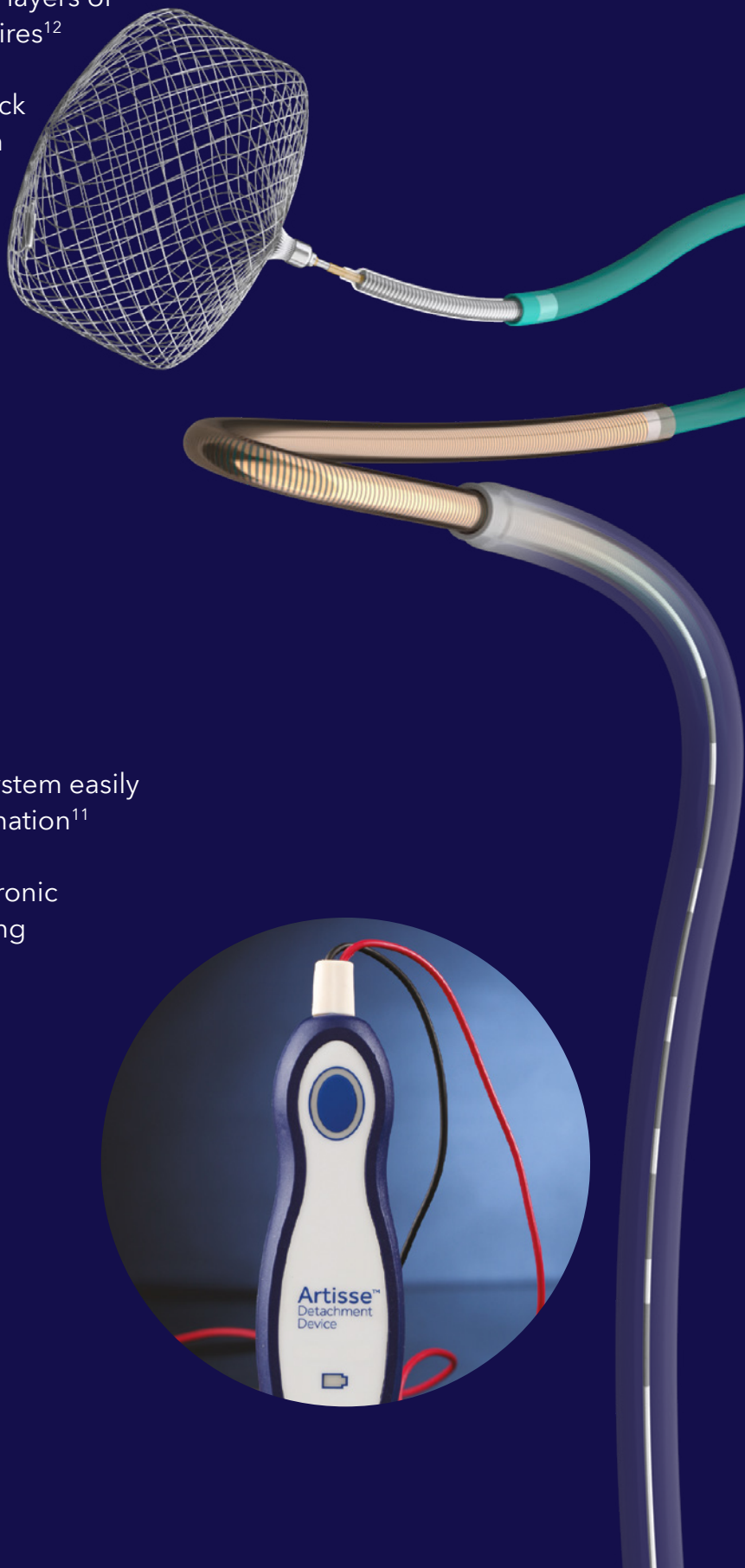
Conformability.
Control.
Reliability.
Safety.

Highly conformable; flex-to-fit technology to take the shape of the aneurysm[12]

Conformability

Artisse™ is highly conformable, meaning it flexes to fit the unique aneurysm shape while providing stability.[1-4,12]

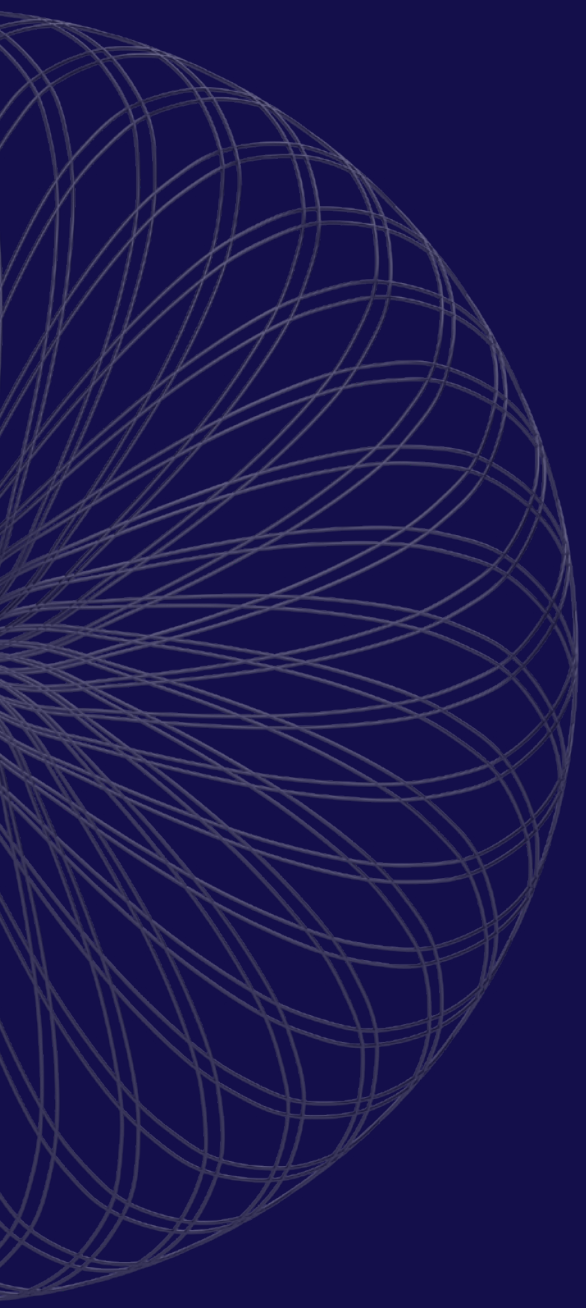
- Artisse™ provides a high degree of conformability to the aneurysm shape and neck[14], thanks to the unique engineering of its basket made from two layers of high-density platinum core nitinol DFT wires[12]
- Effective flow diversion created at the neck with uniform radial force at the aneurysm equator[2,4]
- Optimum outward radial force to fill the space and provide stability[4,5,6]
- Versatile device placement through 021 delivery, and packaged unconstrained, ready to deploy effectively that results in a secure fit*[1-4,10]



Reliability

Proven reliability you can see and hear.[7,11]

- The handheld electrolytic detachment system easily deploys and provides immediate confirmation[11]
- Simulation software, backed up by Medtronic one-to-one support, enables precise sizing selection[14]
- Visible gap on the delivery wire serves as confirmation of detachment[3]
- Medtronic, is a global leader in medical technology, serving more than 76 million patients worldwide



Control

Feels smooth, steady and predictable in your hands during deployment to help treat with confidence, precision and speed.[7,14]

- The nitinol delivery wire has intuitive push and pull movements, so you feel in control and the device behaves predictably[10]
- The DFT mesh construction provides excellent visibility, helping you guide and position the device[3]
- Simple-to-use, Artisse™ is faster when compared with coils, balloon or stent assisted coiling[13]

Safety

Atraumatic design at every step. From the smooth distal tip to the device deployment, Artisse™ is designed to reduce risk to, and stress on, the aneurysm walls.[3,9]

- The distal tip design protects the aneurysm dome during deployment even when it's not fully deployed – so you can have confidence during positioning, repositioning, deployment and detachment[3]
- Artisse™ exerts less force per area on the aneurysm dome than WEB[12]
- The platinum core nitinol DFT wires that make up Artisse™ provide excellent visibility under fluoroscopy, making it easy to track and position accurately during the procedure[3]
- Artisse™ shows higher radiopacity values than WEB for equivalent device sizes, making it easier to visualize during tracking and positioning[12]
- Artisse™ has no gathering point at the distal tip and is smooth and flexible[3]
- Deployment is controlled and stable, gently 'flowering'[9]

Artisse™ device

CFN	(W x H), mm
ISF-045-030	4.5 x 3.0
ISF-045-040	4.5 x 4.0
ISF-050-030	5.0 x 3.0
ISF-050-040	5.0 x 4.0
ISF-055-030	5.5 x 3.0
ISF-055-040	5.5 x 4.0
ISF-055-050	5.5 x 5.0
ISF-060-030	6.0 x 3.0

CFN	(W x H), mm
ISF-060-040	6.0 x 4.0
ISF-060-050	6.0 x 5.0
ISF-065-030	6.5 x 3.0
ISF-065-040	6.5 x 4.0
ISF-065-050	6.5 x 5.0
ISF-070-030	7.0 x 3.0
ISF-070-040	7.0 x 4.0
ISF-070-050	7.0 x 5.0

CFN	(W x H), mm
ISF-075-040	7.5 x 4.0
ISF-075-050	7.5 x 5.0
ISF-080-040	8.0 x 4.0
ISF-080-050	8.0 x 5.0

Artisse™ detachment device

Reference Number	Description
ISD-5-PK	Artisse™ Detachment Device (5-pack)

References:

1. Data on File D00360690 Artisse 2 Design Verification Implant Shape and Chronic Outward Force Report. 23-Nov-2020.
2. Data on File D00662662 Artisse 2 Rabbit Vessel Pouch Aneurysm GLP Animal Study Design Validation Report. Testing performed with 14 rabbits with a preexisting surgically created elastase induced aneurysm. 06-Nov-2023.
3. Data on File M810805ADOC1 Artisse Implant Subassembly. 18-Sep-2023.
4. Data on File D00789514 Artisse 2 25% Compression Radial Force Design Verification Testing Report. 02- Sep-2022.
5. Data on File. D00360690_A. D00662662. D00363440_A
6. HCP VOC FY22-23, in lab and gathered at conferences
7. Data on File TR-NV12962 Artisse-021 System Design Validation Report. 19-Jul-2016. D00357033 Artisse 2 Intrasaccular Device Design Validation Report. 17- Nov-2020.
8. Data on File. : Artisse and Rebar-18 Microcatheter Design Verification Testing
9. Data on File. D00314111_A_Appendix 7: Feasibility Testing and FEA Artisse-II DVT Justification Engineering Memo
10. Data on File. DWGS31534- Pusher, Artisse. 13-Dec-22
11. Data on File. TR-NV12721_A: Artisse-021 Detachment and Kink Resistance Test Report. Artisse Detachment Device IFU M993509ADOC2 Rev C
12. Data on File. D01177929 Rev A Competitive testing report, intrasaccular device competitive evaluation.
13. Fiorella D, Molyneux A, Coon A, Szikora I, Demographic, procedural and 30-day safety results from the WEB Intra-saccular Therapy Study (WEB-IT).

Indications for use:
The Artisse™ Intrasaccular Device is intended for the endovascular embolization of saccular intracranial aneurysms.

Caution:
Federal law restricts these devices to sale, distribution, and use by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labeling supplied with each device.

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.eu

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