Johnson & Johnson
MEDICAL COMPANIES

CERENOVUS CEREBASE™ DA Guide Sheath

세레노부스 CEO 마크 디킨슨(Mark Dickinson) 은 "뇌졸중은 몇 분 안에 생명을 앗아갈 수 있는 조용한 살인마이며 우리는 의사가 환자를 효율적이고 효과적으로 치료할 수 있도록 지원하기 위해 세레노버스 뇌졸중 솔루션을 설계했다"고 말했습니다. 그는 "뇌졸중 치료의 궤적을 바꾸기 위해 의료진들의 실제 경험을 바탕으로 차별화된 솔루션을 개발하는데 전념하고 있다"고 덧붙였습니다. – ESMINT;

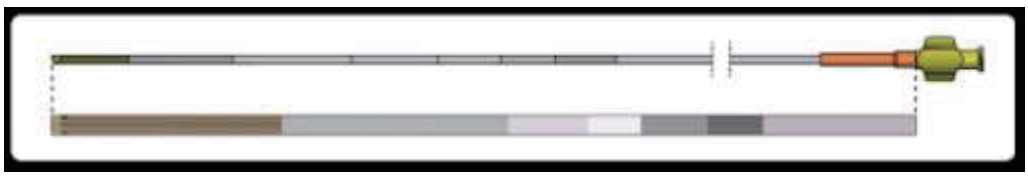
Cerenovus는 최근 혈전 제거 시술에서 의료진들을 시술을 돕기 위해 설계된 세 가지 디바이스로 구성된 Stroke Solutions를 출시한다고 발표했습니다.

세 가지 디바이스 중, Long Guide Sheath 제품인 CEREBASE DA는 의료진들이 어려운 해부학적 구조에서 네비게이션하고 distal access를 확보할 수 있도록 높은 TRACKABILITY와 SUPPORT를 제공하는 것을 목표로 합니다.

CEREBASE™ DA Key Features

Key features of CEREBASE™ DA include:

- Large inner diameter to accommodate different treatment options [10]
- Trackability to distal ICA, including cervical and first petrous bends [2,10]
- Single nonsplit radiopaque platinum marker band [2,10]
- Outer hydrophilic coating on distal 20 cm provides lubricious coating that reduces friction during use
- Multiple segment lengths of varying durometer for smooth transition zones [10]
- Continuous stainless steel braidwire reinforced wall with continuous inner PTFE liner [2]



CERENOVUS CEREBASE™ DA Guide Sheath

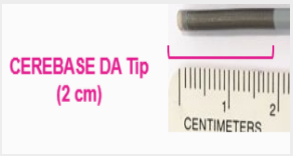
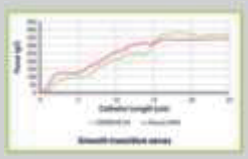
CEREBASE™ DA Guide Sheath Offerings

Catalog #	Short Sheath Compatibility	ID	OD	Length
GS9080SD	8F	0.090”	8F	80 cm
GS9090SD	8F	0.090”	8F	90 cm
GS9095SD	8F	0.090”	8F	95 cm

Reminder: 0.090” ID falls into the 6F long sheath category

CEREBASE™ DA Design Features and Clinical Benefit

Trackability

Feature	Description	Clinical Benefit	Image
Dextrous (DEX) tip	Distal 2 cm has highly flexible DEX tip	• Facilitates tight turns, providing trackability to distal anatomy • Gets closer to target site	
Soft tip[2]	Soft, compliant, and rounded tip	• Minimizes direct vessel contact • Allows for atraumatic vessel wall interaction	
Smooth transition zones[2]	Smooth transition zones along length of catheter	• Allows transfer of control from • proximal end to distal tip	
Kink resistance[2]	High kink resistance in thin wall design	• High kink resistance • Maintains catheter lumen	

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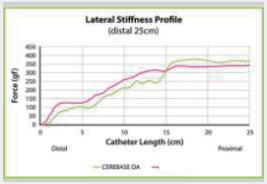
Support

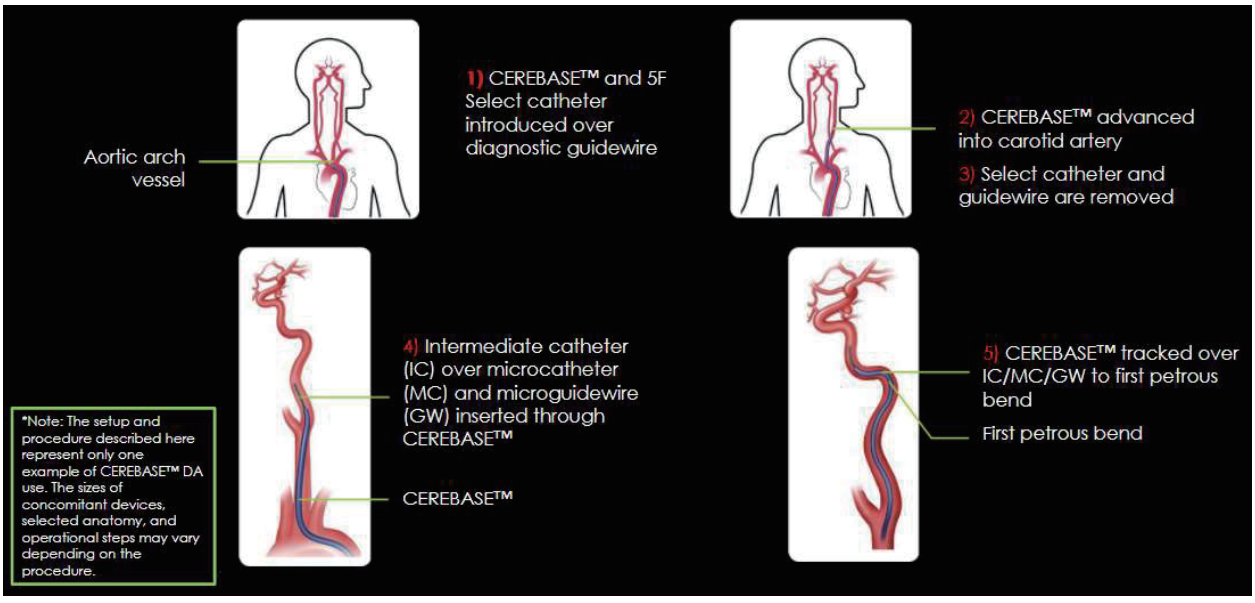
Feature	Description	Clinical Benefit
Distal tracking[8]	Engineered to secure distal access for geometric anchoring	Anchoring of catheter in various bends provides more procedural support*
Proximal shaft stiffness[2]	High proximal shaft stiffness designed for arch support	Requires more force to bend/impact catheter; backup support aided by shaft stiffness
Stiffness to flexibility profile	Gradual transition to lower stiffness toward distal end	Provides smooth transition zones along length of catheter body, transferring control from proximal end to distal tip
Use in ischemic and hemorrhagic cases[2,10]	Many features support use in ischemic and hemorrhagic stroke	

Geometric anchoring in petrous and cervical bends[14]



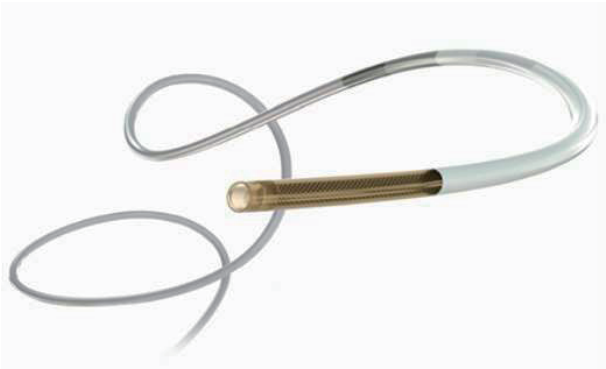
Feature	Ischemic Stroke	Hemorrhagic Stroke
Tortuous anatomy tracking	• Complex arch and tortuous vessels	• Complex arch tortuous vessels
Procedural support	• Deliver/retrieve devices	• Deliver flow diverters, intravascular
Large ID	• More room for large aspiration catheters, clot	• More room for multiple in-dwelling devices
Distal tracking	• Closer to clot; flow modification	• Additional support due to geometric anchoring

CEREBASE™ DA Placement*



CERENOVUS CEREBASE™ DA Guide Sheath

CEREBASE™ DA Guide Sheath Use



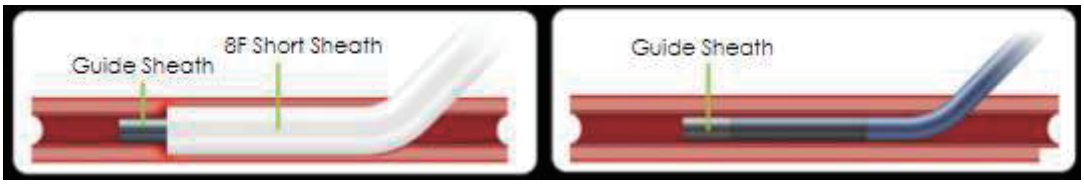
Instructions for Use

1. Select an appropriately sized CEREBASE DA Guide Sheath based on the patient anatomy and length.
2. Gently remove the device and accessories from the packaging.
3. Inspect the guide sheath upon removal from packaging to verify that it is undamaged.

   CAUTION: Do not use a guide sheath, dilator, or hemostasis valve that has been damaged in any way. If damage is detected, replace with another guide sheath, dilator, or hemostasis valve that is not damaged.
4. Prior to use, flush the lumen of the guide sheath and wet the outer body of the catheter with a heparinized saline solution. Connect a hemostasis valve to the hub of the guide sheath. Set up a continuous heparinized saline flush through the hemostasis valve.

CEREBASE™ DA IFU and Use

- The CEREBASE™ DA is indicated for the introduction of interventional devices into the neurovasculature
- There are no known contraindications
- The IFU lists 7 warnings, including directions for preventing thrombus formation and contrast media crystal formation
- The IFU lists 9 precautions, including maintaining hydration of the hydrophilic coating on the guide sheath if removed from the patient
- The IFU includes general instructions for use
- The CEREBASE™ DA can be used with or without a short sheath



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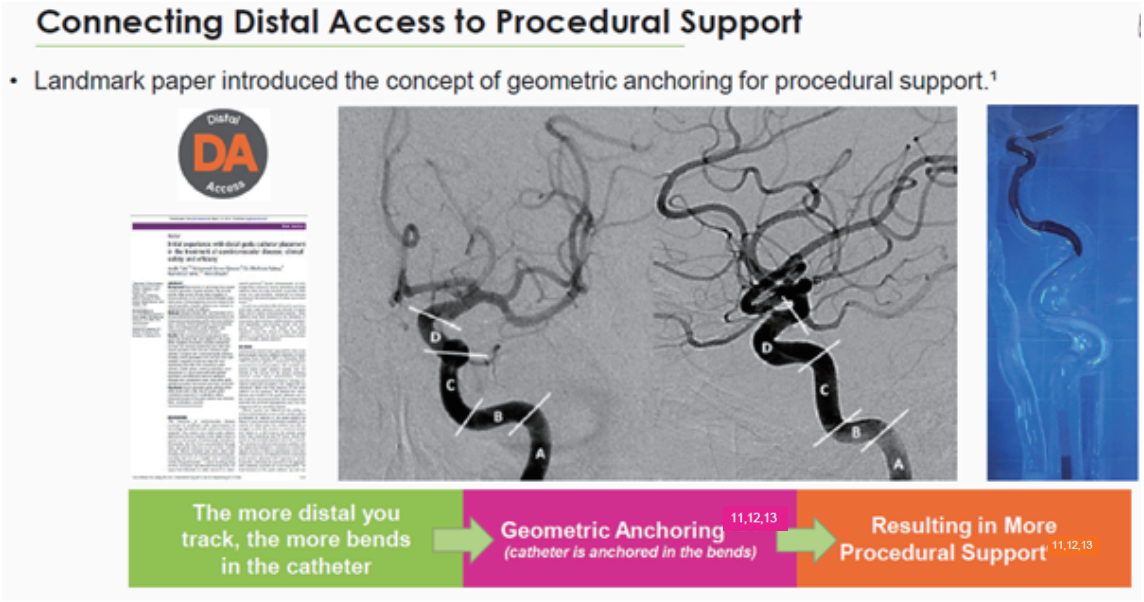
2012년 발표된 논문에 따르면 Guide Catheter를 사용한 경우, distal access에 용이하게 하는 동시에 낮은 complication 발생율을 확인할 수 있었습니다.[11]



References

2. Cerenovus internal report. 103664599.
8. Turk A, Manzoor MU, Nyberg EM, Turner RD, and Chaudry I. Initial experience with distal guide catheter placement in the treatment of cerebrovascular disease: clinical safety and efficacy. J Neurointervent Surg. 2013;5:247-252.
10. Cerenovus internal report. DD-056
11."Initial experience with distal guide catheter placement in the treatment of cerebrovascular disease: clinical safety and efficacy", Turk A, Manzoor MU, Nyberg EM, et al. J NeuroIntervent Surg (2012)
12. CEREBASE DA Benchtop Competitive Test Report, 103664599, Rev.1, May 2020, Data on file
13. CEREBASE DA Benchtop Competitive Test Report 103618595, April 2020, Data on file