

iCast[®] covered stent system

Technical specifications

Stent Specifications

| | |
|----------------|------------------------------------|
| Stent Material | 316L stainless steel |
| Stent Design | Single stent with open cell design |
| Stent Covering | Fully encapsulated in ePTFE |

Balloon Catheter Specifications

| | |
|------------------------------|--|
| Delivery System | Premounted on balloon catheter |
| Balloon Type | Non-compliant |
| Balloon Material | PET |
| Balloon Nominal Pressure | 8 atm (5-12 mm diameter) |
| Balloon Rated Burst Pressure | 12 atm (5-10 mm diameter), 10 atm (12 mm diameter) |
| Markers | Gold |

Size & Dimensions

| | |
|-----------------------|--|
| Stent Diameters | 5-12 mm (see table below) |
| Stent Lengths | for 5-10 mm diameters: 16 mm, 22 mm, 32 mm, 38 mm, 59 mm for 12 mm diameters: 29 mm, 41 mm, 61 mm |
| Wire Guide Diameter | 0.035 inch |
| Catheter Shaft Length | 80 cm, 120 cm |
| Introducer Sheath | 6 Fr, 7 Fr, 9 Fr |

Other

| | |
|----------------------|-----------------|
| Shelf Life | 3 years |
| Sterilization Method | Ethylene oxide |
| Use | Single use only |

Indications for Use

For improving luminal diameter in patients with symptomatic atherosclerotic disease of the native common and/or external iliac arteries up to 110 mm in length, with a reference vessel diameter of 5 to 12 mm. It is also indicated for use as a bridging stent between a branch vessel and an endovascular graft. This is limited to endovascular grafts that are approved for use with the iCast covered stent as a bridging stent, for treatment of patients with aneurysmal disease.^a

Max. Recommended Post-Dilation Diameter mm (for 5-10 mm Diameter)

| Labeled Diameter mm | Device Length ^b mm | | | | |
|---------------------|-------------------------------|-----|-----|------|------|
| | 16 | 22 | 32 | 38 | 59 |
| 5 | 7.3 | 7.3 | 9.3 | 9.8 | 9.8 |
| 6 | 7.3 | 7.3 | 9.3 | 10.0 | 10.0 |
| 7 | 7.3 | 7.3 | 9.3 | 10.1 | 10.1 |
| 8 | - | - | 9.3 | 10.2 | 10.2 |
| 9 | - | - | 9.3 | 10.4 | 10.4 |
| 10 | - | - | - | 10.6 | - |

Max. Recommended Post-Dilation Diameter mm (for 12 mm Diameter)

| Labeled Diameter mm | Device Length ^b mm | | |
|---------------------|-------------------------------|------|------|
| | 29 | 41 | 61 |
| 12 | 16.0 | 16.0 | 16.0 |



Balloon Outer Diameter (OD)


| | 5 mm | 6 mm | 7 mm | 8 mm | 9 mm | 10 mm | 12 mm |
|---------------------------------|------|------|------|------|------|-------|-------|
| Nominal Pressure atm | 5.1 | 6.1 | 7.1 | 8.2 | 9.1 | 10.2 | 12.3 |
| Rated Burst Pressure atm | 5.3 | 6.3 | 7.3 | 8.5 | 9.4 | 10.5 | 12.4 |

| Stent Diameter/ Length ^a mm | Cook GPN 80 cm Catheter Length | Cook RPN/ Getinge Code 80 cm Catheter Length | Cook GPN 120 cm Catheter Length | Cook RPN/ Getinge Code 120 cm Catheter Length | Post Nominal Pressure 8 atm | | Post Rated Burst Pressure 12 atm | | Introducer Compatibility Fr |
|--|--------------------------------------|---|--|--|--------------------------------------|---------------------------|--------------------------------------|---------------------------|-----------------------------------|
| | | | | | Outer Diameter ^b mm | Length ^b mm | Outer Diameter ^b mm | Length ^b mm | |
| 5 x 16 | G60480 | 48516 | G60497 | 42516 | 4.9 | 15.9 | 5.2 | 15.6 | 6 |
| 5 x 22 | G60481 | 48522 | G60498 | 42522 | 4.9 | 21.3 | 5.2 | 21.0 | 6 |
| 5 x 32 | G61753 | 48532 | G61759 | 42532 | 5.0 | 32.3 | 5.3 | 32.3 | 7 |
| 5 x 38 | G60482 | 48538 | G60499 | 42538 | 5.1 | 37.2 | 5.3 | 37.7 | 7 |
| 5 x 59 | G60483 | 48559 | G60500 | 42559 | 5.0 | 58.6 | 5.3 | 60.0 | 7 |
| 6 x 16 | G60484 | 48616 | G60501 | 42616 | 5.7 | 15.7 | 6.2 | 15.1 | 6 |
| 6 x 22 | G60485 | 48622 | G60502 | 42622 | 5.8 | 20.8 | 6.2 | 20.2 | 6 |
| 6 x 32 | G61754 | 48632 | G61760 | 42632 | 5.9 | 31.7 | 6.3 | 31.5 | 7 |
| 6 x 38 | G60486 | 48638 | G60503 | 42638 | 6.0 | 36.6 | 6.3 | 37.0 | 7 |
| 6 x 59 | G60487 | 48659 | G60504 | 42659 | 6.0 | 57.8 | 6.3 | 58.7 | 7 |
| 7 x 16 | G60488 | 48716 | G60505 | 42716 | 6.9 | 15.0 | 7.3 | 14.2 | 7 |
| 7 x 22 | G60489 | 48722 | G60506 | 42722 | 6.9 | 20.1 | 7.3 | 19.4 | 7 |
| 7 x 32 | G61755 | 48732 | G61761 | 42732 | 6.9 | 31.3 | 7.3 | 31.2 | 7 |
| 7 x 38 | G60490 | 48738 | G60507 | 42738 | 6.9 | 35.8 | 7.3 | 35.7 | 7 |
| 7 x 59 | G60491 | 48759 | G60508 | 42759 | 7.0 | 57.1 | 7.3 | 57.5 | 7 |
| 8 x 32 | G61756 | 48832 | G61762 | 42832 | 7.9 | 30.0 | 8.4 | 29.6 | 7 |
| 8 x 38 | G60492 | 48838 | G60509 | 42838 | 8.1 | 34.7 | 8.5 | 34.7 | 7 |
| 8 x 59 | G60493 | 48859 | G60510 | 42859 | 8.0 | 56.0 | 8.4 | 56.5 | 7 |
| 9 x 32 | G61757 | 48932 | G61763 | 42932 | 8.9 | 28.7 | 9.3 | 29.2 | 7 |
| 9 x 38 | G60494 | 48938 | G60511 | 42938 | 8.9 | 33.7 | 9.3 | 32.7 | 7 |
| 9 x 59 | G60495 | 48959 | G60512 | 42959 | 8.9 | 54.6 | 9.3 | 54.0 | 7 |
| 10 x 38 | G60496 | 48038 | G60513 | 42038 | 10.0 | 30.8 | 10.4 | 30.9 | 7 ^a |
| 10 x 59 | G61758 | 48059 | G61764 | 72059 | 9.9 | 53.3 | 10.3 | 52.5 | 7 ^a |

Please follow any step-by-step instructions carefully, including the risk and technical information provided in the IFU. Note that some products or part numbers may not be available in all markets; consult your Cook representative for details.

| Stent Diameter/ Length mm | Cook GPN 80 cm Catheter Length | Cook RPN/ Getinge Code 80 cm Catheter Length | Cook GPN 120 cm Catheter Length | Cook RPN/ Getinge Code 120 cm Catheter Length | Post Nominal Pressure 8 atm | | Post Rated Burst Pressure 10 atm | | Introducer Compatibility Fr |
|---------------------------------|--------------------------------------|---|--|--|--------------------------------------|---------------------------|--------------------------------------|---------------------------|-----------------------------------|
| | | | | | Outer Diameter ^b mm | Length ^b mm | Outer Diameter ^b mm | Length ^b mm | |
| 12 x 29 ^c | G61747 | GBX12291A | G61750 | GBX12292A | 11.1 | 25.6 | 11.4 | 25.3 | 9 |
| 12 x 41 ^c | G61748 | GBX12411A | G61751 | GBX12412A | 11.2 | 37.6 | 11.6 | 37.1 | 9 |
| 12 x 61 ^c | G61749 | GBX12611A | G61752 | GBX12612A | 11.2 | 58.2 | 11.6 | 57.6 | 9 |

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- a. If using a 10 mm device with a Cook introducer sheath, it is recommended to use an 8 Fr sheath to minimize potential for resistance.
- b. Provided as general guidance based on averages observed during in vitro testing.
- c. 12 mm sizes (including post-dilation to 16 mm) have not been evaluated for use as bridging stents.



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iCast covered stent