

enVast™ CORONARY THROMBECTOMY SYSTEM

TECHNICAL SPECIFICATIONS

| enVast Size | Product Code | GTIN | Maximal Diameter (mm) | Working Length (mm) | Full Length (mm) | No. of Drop Zones | Recommended Vessel Diameter (mm) | Min. DC ID |
|-----------------|--------------|----------------|-----------------------|---------------------|------------------|-------------------|----------------------------------|------------|
| enVast 4.0 x 30 | EV-4030-F2RR | 00851279008699 | 4.0 | 30 | 48 | 2 | ≥ 2.0 & ≤ 3.5 | .021" |
| enVast 4.5 x 37 | EV-4537-F2RR | 00851279008712 | 4.5 | 37 | 57 | 2 | ≥ 2.0 & ≤ 4.5 | .021" |
| enVast 4.5 x 46 | EV-4546-F3RR | 00851279008729 | 4.5 | 46 | 66 | 3 | ≥ 2.0 & ≤ 4.5 | .021" |
| enVast 6.0 x 35 | EV-6035-F2RR | 00851279008736 | 6.0 | 35 | 55 | 2 | ≥ 3.5 & ≤ 6.0 | .027" |

| Parameter | Specifications |
|---------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| Material | Basket: laser cut from nitinol tube Pusherwire: nitinol Fluoro-opaque markers: platinum & tungsten |
| Distal tip | 5 mm, soft and flexible, platinum coil wind over tapered nitinol core |
| Pusherwire | 200 cm |
| Fluoro Markers | "Zebra" marker band on the pusher wire: 8 cm-long section of 1-cm silver bands, placed 68.5 cm to 76.5 cm from the proximal end on the pusherwire |
| Radial Force | Radial force optimized: higher expansive forces for efficacy in clot interaction and lower compressive forces for vessel safety |
| Tensile Strength | .083" lbf (minimum) |
| Torque Strength | 10 cycles without damage to device |
| Re-Sheathing | Up to 3 times |
| Radio-Detectability | enVast is easily visualized under fluoroscopy : 1 marker at the proximal juncture of the basket, 2 per each Drop Zone, and visible distal tip |
| Packaging & Sterilization | Individually packaged and ETO sterilized per ISO 11135: 2014 |
| Shelf-life | 3 years maximum from date of manufacture |
| Corrosion Resistance | No sign of corrosion |
| Biocompatibility | Biocompatible per ISO 10993-1 |
| Latex | No known latex material used in the manufacturing of the device |
| Labeling | Device to have descriptive labels identifying the content in compliance with EN ISO 15223-1 and EN 1041 |
| Storage Conditions | Room temperature |