**Rx ONLY.**

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician

## WARNING

Contents supplied STERILE using a EO sterilization process. Do not use if sterile barrier is damaged.

Use the catheter prior to the "Use By" date specified on the package.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or reserialization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient

## DEVICE DESCRIPTION

The Peripheral Scoring Balloon Dilatation Catheter features a non-compliant balloon with 3 scoring elements mounted longitudinally on its outer surface. When the Peripheral Scoring Balloon Dilatation Catheter is inflated, the scoring elements score intima tissue to achieve the purpose of treatment. It is designed to improve the lumen diameter of obstructive lesions in peripheral vessels.

The Peripheral Scoring Balloon Dilatation Catheter is an over the wire (OTW), high performance, double-lumen catheter. 3 scoring elements between the two marker bands are evenly circle mounted on the surface of the balloon. The catheter has two independent lumens, one lumen is used for filling the balloon, and the other lumen is used for guide wire insertion. There are two radiopaque marker bands in the balloon for positioning, which indicates the expanded part of the balloon and helps in the placement of the balloon.

The diameter and length of the balloon and the diameter of the compatible guide wire are printed on the seat.

The sterile barrier system of the product contains a protective hoop to hold the catheter.

## SIZE

| NO. | Model Number | Balloon Nominal Diameter (mm) | Balloon Nominal Length (mm) | Catheter length (cm) | Balloon Nominal Pressure (atm) | Rated Burst Pressure (atm) |
|---|---|---|---|---|---|---|
| 1 | DKL14-2520B | 2.5 | 20 | 90 | 10 | 14 |
| 2 | DKL14-2540B | 2.5 | 40 | 90 | 10 | 14 |
| 3 | DKL14-2560B | 2.5 | 60 | 90 | 10 | 14 |
| 4 | DKL14-2580B | 2.5 | 80 | 90 | 10 | 14 |
| 5 | DKL14-25100B | 2.5 | 100 | 90 | 10 | 14 |
| 6 | DKL14-25120B | 2.5 | 120 | 90 | 10 | 14 |
| 7 | DKL14-25150B | 2.5 | 150 | 90 | 10 | 14 |
| 8 | DKL14-2520C | 2.5 | 20 | 135 | 10 | 14 |
| 9 | DKL14-2540C | 2.5 | 40 | 135 | 10 | 14 |
| 10 | DKL14-2560C | 2.5 | 60 | 135 | 10 | 14 |

| NO. | Model Number | Balloon Nominal Diameter (mm) | Balloon Nominal Length (mm) | Catheter length (cm) | Balloon Nominal Pressure (atm) | Rated Burst Pressure (atm) |
|---|---|---|---|---|---|---|
| 11 | DKL14-2580C | 2.5 | 80 | 135 | 10 | 14 |
| 12 | DKL14-25100C | 2.5 | 100 | 135 | 10 | 14 |
| 13 | DKL14-25120C | 2.5 | 120 | 135 | 10 | 14 |
| 14 | DKL14-25150C | 2.5 | 150 | 135 | 10 | 14 |
| 15 | DKL14-2520D | 2.5 | 20 | 150 | 10 | 14 |
| 16 | DKL14-2540D | 2.5 | 40 | 150 | 10 | 14 |
| 17 | DKL14-2560D | 2.5 | 60 | 150 | 10 | 14 |
| 18 | DKL14-2580D | 2.5 | 80 | 150 | 10 | 14 |
| 19 | DKL14-25100D | 2.5 | 100 | 150 | 10 | 14 |
| 20 | DKL14-25120D | 2.5 | 120 | 150 | 10 | 14 |
| 21 | DKL14-25150D | 2.5 | 150 | 150 | 10 | 14 |
| 22 | DKL14-3020B | 3.0 | 20 | 90 | 10 | 14 |
| 23 | DKL14-3040B | 3.0 | 40 | 90 | 10 | 14 |
| 24 | DKL14-3060B | 3.0 | 60 | 90 | 10 | 14 |
| 25 | DKL14-3080B | 3.0 | 80 | 90 | 10 | 14 |
| 26 | DKL14-30100B | 3.0 | 100 | 90 | 10 | 14 |
| 27 | DKL14-30120B | 3.0 | 120 | 90 | 10 | 14 |
| 28 | DKL14-30150B | 3.0 | 150 | 90 | 10 | 14 |
| 29 | DKL14-3020C | 3.0 | 20 | 135 | 10 | 14 |
| 30 | DKL14-3040C | 3.0 | 40 | 135 | 10 | 14 |
| 31 | DKL14-3060C | 3.0 | 60 | 135 | 10 | 14 |
| 32 | DKL14-3080C | 3.0 | 80 | 135 | 10 | 14 |
| 33 | DKL14-30100C | 3.0 | 100 | 135 | 10 | 14 |
| 34 | DKL14-30120C | 3.0 | 120 | 135 | 10 | 14 |
| 35 | DKL14-30150C | 3.0 | 150 | 135 | 10 | 14 |
| 36 | DKL14-3020D | 3.0 | 20 | 150 | 10 | 14 |
| 37 | DKL14-3040D | 3.0 | 40 | 150 | 10 | 14 |
| 38 | DKL14-3060D | 3.0 | 60 | 150 | 10 | 14 |
| 39 | DKL14-3080D | 3.0 | 80 | 150 | 10 | 14 |
| 40 | DKL14-30100D | 3.0 | 100 | 150 | 10 | 14 |
| 41 | DKL14-30120D | 3.0 | 120 | 150 | 10 | 14 |
| 42 | DKL14-30150D | 3.0 | 150 | 150 | 10 | 14 |
| 43 | DKL14-3520B | 3.5 | 20 | 90 | 10 | 14 |

| NO. | Model Number | Balloon Nominal Diameter (mm) | Balloon Nominal Length (mm) | Catheter length (cm) | Balloon Nominal Pressure (atm) | Rated Burst Pressure (atm) |
|---|---|---|---|---|---|---|
| 44 | DKL14-3540B | 3.5 | 40 | 90 | 10 | 14 |
| 45 | DKL14-3560B | 3.5 | 60 | 90 | 10 | 14 |
| 46 | DKL14-3580B | 3.5 | 80 | 90 | 10 | 14 |
| 47 | DKL14-35100B | 3.5 | 100 | 90 | 10 | 14 |
| 48 | DKL14-35120B | 3.5 | 120 | 90 | 10 | 14 |
| 49 | DKL14-35150B | 3.5 | 150 | 90 | 10 | 14 |
| 50 | DKL14-3520C | 3.5 | 20 | 135 | 10 | 14 |
| 51 | DKL14-3540C | 3.5 | 40 | 135 | 10 | 14 |
| 52 | DKL14-3560C | 3.5 | 60 | 135 | 10 | 14 |
| 53 | DKL14-3580C | 3.5 | 80 | 135 | 10 | 14 |
| 54 | DKL14-35100C | 3.5 | 100 | 135 | 10 | 14 |
| 55 | DKL14-35120C | 3.5 | 120 | 135 | 10 | 14 |
| 56 | DKL14-35150C | 3.5 | 150 | 135 | 10 | 14 |
| 57 | DKL14-3520D | 3.5 | 20 | 150 | 10 | 14 |
| 58 | DKL14-3540D | 3.5 | 40 | 150 | 10 | 14 |
| 59 | DKL14-3560D | 3.5 | 60 | 150 | 10 | 14 |
| 60 | DKL14-3580D | 3.5 | 80 | 150 | 10 | 14 |
| 61 | DKL14-35100D | 3.5 | 100 | 150 | 10 | 14 |
| 62 | DKL14-35120D | 3.5 | 120 | 150 | 10 | 14 |
| 63 | DKL14-35150D | 3.5 | 150 | 150 | 10 | 14 |
| 64 | DKL18-4020B | 4.0 | 20 | 90 | 10 | 14 |
| 65 | DKL18-4040B | 4.0 | 40 | 90 | 10 | 14 |
| 66 | DKL18-4060B | 4.0 | 60 | 90 | 10 | 14 |
| 67 | DKL18-4080B | 4.0 | 80 | 90 | 10 | 14 |
| 68 | DKL18-40100B | 4.0 | 100 | 90 | 10 | 14 |
| 69 | DKL18-40120B | 4.0 | 120 | 90 | 10 | 14 |
| 70 | DKL18-40150B | 4.0 | 150 | 90 | 10 | 14 |
| 71 | DKL18-4020C | 4.0 | 20 | 135 | 10 | 14 |
| 72 | DKL18-4040C | 4.0 | 40 | 135 | 10 | 14 |
| 73 | DKL18-4060C | 4.0 | 60 | 135 | 10 | 14 |
| 74 | DKL18-4080C | 4.0 | 80 | 135 | 10 | 14 |
| 75 | DKL18-40100C | 4.0 | 100 | 135 | 10 | 14 |
| 76 | DKL18-40120C | 4.0 | 120 | 135 | 10 | 14 |

| NO. | Model Number | Balloon Nominal Diameter (mm) | Balloon Nominal Length (mm) | Catheter length (cm) | Balloon Nominal Pressure (atm) | Rated Burst Pressure (atm) |
|---|---|---|---|---|---|---|
| 77 | DKL18-40150C | 4.0 | 150 | 135 | 10 | 14 |
| 78 | DKL18-4020D | 4.0 | 20 | 150 | 10 | 14 |
| 79 | DKL18-4040D | 4.0 | 40 | 150 | 10 | 14 |
| 80 | DKL18-4060D | 4.0 | 60 | 150 | 10 | 14 |
| 81 | DKL18-4080D | 4.0 | 80 | 150 | 10 | 14 |
| 82 | DKL18-40100D | 4.0 | 100 | 150 | 10 | 14 |
| 83 | DKL18-40120D | 4.0 | 120 | 150 | 10 | 14 |
| 84 | DKL18-40150D | 4.0 | 150 | 150 | 10 | 14 |
| 85 | DKL18-4520B | 4.5 | 20 | 90 | 10 | 14 |
| 86 | DKL18-4540B | 4.5 | 40 | 90 | 10 | 14 |
| 87 | DKL18-4560B | 4.5 | 60 | 90 | 10 | 14 |
| 88 | DKL18-4580B | 4.5 | 80 | 90 | 10 | 14 |
| 89 | DKL18-45100B | 4.5 | 100 | 90 | 10 | 14 |
| 90 | DKL18-45120B | 4.5 | 120 | 90 | 10 | 14 |
| 91 | DKL18-45150B | 4.5 | 150 | 90 | 10 | 14 |
| 92 | DKL18-4520C | 4.5 | 20 | 135 | 10 | 14 |
| 93 | DKL18-4540C | 4.5 | 40 | 135 | 10 | 14 |
| 94 | DKL18-4560C | 4.5 | 60 | 135 | 10 | 14 |
| 95 | DKL18-4580C | 4.5 | 80 | 135 | 10 | 14 |
| 96 | DKL18-45100C | 4.5 | 100 | 135 | 10 | 14 |
| 97 | DKL18-45120C | 4.5 | 120 | 135 | 10 | 14 |
| 98 | DKL18-45150C | 4.5 | 150 | 135 | 10 | 14 |
| 99 | DKL18-4520D | 4.5 | 20 | 150 | 10 | 14 |
| 100 | DKL18-4540D | 4.5 | 40 | 150 | 10 | 14 |
| 101 | DKL18-4560D | 4.5 | 60 | 150 | 10 | 14 |
| 102 | DKL18-4580D | 4.5 | 80 | 150 | 10 | 14 |
| 103 | DKL18-45100D | 4.5 | 100 | 150 | 10 | 14 |
| 104 | DKL18-45120D | 4.5 | 120 | 150 | 10 | 14 |
| 105 | DKL18-45150D | 4.5 | 150 | 150 | 10 | 14 |
| 106 | DKL18-5020B | 5.0 | 20 | 90 | 10 | 14 |
| 107 | DKL18-5040B | 5.0 | 40 | 90 | 10 | 14 |
| 108 | DKL18-5060B | 5.0 | 60 | 90 | 10 | 14 |
| 109 | DKL18-5080B | 5.0 | 80 | 90 | 10 | 14 |

| NO. | Model Number | Balloon Nominal Diameter (mm) | Balloon Nominal Length (mm) | Catheter length (cm) | Balloon Nominal Pressure (atm) | Rated Burst Pressure (atm) |
|---|---|---|---|---|---|---|
| 110 | DKL18-50100B | 5.0 | 100 | 90 | 10 | 14 |
| 111 | DKL18-50120B | 5.0 | 120 | 90 | 10 | 14 |
| 112 | DKL18-50150B | 5.0 | 150 | 90 | 10 | 14 |
| 113 | DKL18-5020C | 5.0 | 20 | 135 | 10 | 14 |
| 114 | DKL18-5040C | 5.0 | 40 | 135 | 10 | 14 |
| 115 | DKL18-5060C | 5.0 | 60 | 135 | 10 | 14 |
| 116 | DKL18-5080C | 5.0 | 80 | 135 | 10 | 14 |
| 117 | DKL18-50100C | 5.0 | 100 | 135 | 10 | 14 |
| 118 | DKL18-50120C | 5.0 | 120 | 135 | 10 | 14 |
| 119 | DKL18-50150C | 5.0 | 150 | 135 | 10 | 14 |
| 120 | DKL18-5020D | 5.0 | 20 | 150 | 10 | 14 |
| 121 | DKL18-5040D | 5.0 | 40 | 150 | 10 | 14 |
| 122 | DKL18-5060D | 5.0 | 60 | 150 | 10 | 14 |
| 123 | DKL18-5080D | 5.0 | 80 | 150 | 10 | 14 |
| 124 | DKL18-50100D | 5.0 | 100 | 150 | 10 | 14 |
| 125 | DKL18-50120D | 5.0 | 120 | 150 | 10 | 14 |
| 126 | DKL18-50150D | 5.0 | 150 | 150 | 10 | 14 |
| 127 | DKL18-5520B | 5.5 | 20 | 90 | 10 | 14 |
| 128 | DKL18-5540B | 5.5 | 40 | 90 | 10 | 14 |
| 129 | DKL18-5560B | 5.5 | 60 | 90 | 10 | 14 |
| 130 | DKL18-5580B | 5.5 | 80 | 90 | 10 | 14 |
| 131 | DKL18-55100B | 5.5 | 100 | 90 | 10 | 14 |
| 132 | DKL18-55120B | 5.5 | 120 | 90 | 10 | 14 |
| 133 | DKL18-55150B | 5.5 | 150 | 90 | 10 | 14 |
| 134 | DKL18-5520C | 5.5 | 20 | 135 | 10 | 14 |
| 135 | DKL18-5540C | 5.5 | 40 | 135 | 10 | 14 |
| 136 | DKL18-5560C | 5.5 | 60 | 135 | 10 | 14 |
| 137 | DKL18-5580C | 5.5 | 80 | 135 | 10 | 14 |
| 138 | DKL18-55100C | 5.5 | 100 | 135 | 10 | 14 |
| 139 | DKL18-55120C | 5.5 | 120 | 135 | 10 | 14 |
| 140 | DKL18-55150C | 5.5 | 150 | 135 | 10 | 14 |
| 141 | DKL18-5520D | 5.5 | 20 | 150 | 10 | 14 |
| 142 | DKL18-5540D | 5.5 | 40 | 150 | 10 | 14 |

| NO. | Model Number | Balloon Nominal Diameter (mm) | Balloon Nominal Length (mm) | Catheter length (cm) | Balloon Nominal Pressure (atm) | Rated Burst Pressure (atm) |
|---|---|---|---|---|---|---|
| 143 | DKL18-5560D | 5.5 | 60 | 150 | 10 | 14 |
| 144 | DKL18-5580D | 5.5 | 80 | 150 | 10 | 14 |
| 145 | DKL18-55100D | 5.5 | 100 | 150 | 10 | 14 |
| 146 | DKL18-55120D | 5.5 | 120 | 150 | 10 | 14 |
| 147 | DKL18-55150D | 5.5 | 150 | 150 | 10 | 14 |
| 148 | DKL18-6020B | 6.0 | 20 | 90 | 10 | 14 |
| 149 | DKL18-6040B | 6.0 | 40 | 90 | 10 | 14 |
| 150 | DKL18-6060B | 6.0 | 60 | 90 | 10 | 14 |
| 151 | DKL18-6080B | 6.0 | 80 | 90 | 10 | 14 |
| 152 | DKL18-60100B | 6.0 | 100 | 90 | 10 | 14 |
| 153 | DKL18-60120B | 6.0 | 120 | 90 | 10 | 14 |
| 154 | DKL18-60150B | 6.0 | 150 | 90 | 10 | 14 |
| 155 | DKL18-6020C | 6.0 | 20 | 135 | 10 | 14 |
| 156 | DKL18-6040C | 6.0 | 40 | 135 | 10 | 14 |
| 157 | DKL18-6060C | 6.0 | 60 | 135 | 10 | 14 |
| 158 | DKL18-6080C | 6.0 | 80 | 135 | 10 | 14 |
| 159 | DKL18-60100C | 6.0 | 100 | 135 | 10 | 14 |
| 160 | DKL18-60120C | 6.0 | 120 | 135 | 10 | 14 |
| 161 | DKL18-60150C | 6.0 | 150 | 135 | 10 | 14 |
| 162 | DKL18-6020D | 6.0 | 20 | 150 | 10 | 14 |
| 163 | DKL18-6040D | 6.0 | 40 | 150 | 10 | 14 |
| 164 | DKL18-6060D | 6.0 | 60 | 150 | 10 | 14 |
| 165 | DKL18-6080D | 6.0 | 80 | 150 | 10 | 14 |
| 166 | DKL18-60100D | 6.0 | 100 | 150 | 10 | 14 |
| 167 | DKL18-60120D | 6.0 | 120 | 150 | 10 | 14 |
| 168 | DKL18-60150D | 6.0 | 150 | 150 | 10 | 14 |
| 169 | DKL18-6520B | 6.5 | 20 | 90 | 10 | 14 |
| 170 | DKL18-6540B | 6.5 | 40 | 90 | 10 | 14 |
| 171 | DKL18-6560B | 6.5 | 60 | 90 | 10 | 14 |
| 172 | DKL18-6580B | 6.5 | 80 | 90 | 10 | 14 |
| 173 | DKL18-65100B | 6.5 | 100 | 90 | 10 | 14 |
| 174 | DKL18-65120B | 6.5 | 120 | 90 | 10 | 14 |
| 175 | DKL18-65150B | 6.5 | 150 | 90 | 10 | 14 |

| NO. | Model Number | Balloon Nominal Diameter (mm) | Balloon Nominal Length (mm) | Catheter length (cm) | Balloon Nominal Pressure (atm) | Rated Burst Pressure (atm) |
|---|---|---|---|---|---|---|
| 176 | DKL18-6520C | 6.5 | 20 | 135 | 10 | 14 |
| 177 | DKL18-6540C | 6.5 | 40 | 135 | 10 | 14 |
| 178 | DKL18-6560C | 6.5 | 60 | 135 | 10 | 14 |
| 179 | DKL18-6580C | 6.5 | 80 | 135 | 10 | 14 |
| 180 | DKL18-65100C | 6.5 | 100 | 135 | 10 | 14 |
| 181 | DKL18-65120C | 6.5 | 120 | 135 | 10 | 14 |
| 182 | DKL18-65150C | 6.5 | 150 | 135 | 10 | 14 |
| 183 | DKL18-6520D | 6.5 | 20 | 150 | 10 | 14 |
| 184 | DKL18-6540D | 6.5 | 40 | 150 | 10 | 14 |
| 185 | DKL18-6560D | 6.5 | 60 | 150 | 10 | 14 |
| 186 | DKL18-6580D | 6.5 | 80 | 150 | 10 | 14 |
| 187 | DKL18-65100D | 6.5 | 100 | 150 | 10 | 14 |
| 188 | DKL18-65120D | 6.5 | 120 | 150 | 10 | 14 |
| 189 | DKL18-65150D | 6.5 | 150 | 150 | 10 | 14 |
| 190 | DKL18-7020B | 7.0 | 20 | 90 | 10 | 14 |
| 191 | DKL18-7040B | 7.0 | 40 | 90 | 10 | 14 |
| 192 | DKL18-7060B | 7.0 | 60 | 90 | 10 | 14 |
| 193 | DKL18-7080B | 7.0 | 80 | 90 | 10 | 14 |
| 194 | DKL18-70100B | 7.0 | 100 | 90 | 10 | 14 |
| 195 | DKL18-70120B | 7.0 | 120 | 90 | 10 | 14 |
| 196 | DKL18-70150B | 7.0 | 150 | 90 | 10 | 14 |
| 197 | DKL18-7020C | 7.0 | 20 | 135 | 10 | 14 |
| 198 | DKL18-7040C | 7.0 | 40 | 135 | 10 | 14 |
| 199 | DKL18-7060C | 7.0 | 60 | 135 | 10 | 14 |
| 200 | DKL18-7080C | 7.0 | 80 | 135 | 10 | 14 |
| 201 | DKL18-70100C | 7.0 | 100 | 135 | 10 | 14 |
| 202 | DKL18-70120C | 7.0 | 120 | 135 | 10 | 14 |
| 203 | DKL18-70150C | 7.0 | 150 | 135 | 10 | 14 |
| 204 | DKL18-7020D | 7.0 | 20 | 150 | 10 | 14 |
| 205 | DKL18-7040D | 7.0 | 40 | 150 | 10 | 14 |
| 206 | DKL18-7060D | 7.0 | 60 | 150 | 10 | 14 |
| 207 | DKL18-7080D | 7.0 | 80 | 150 | 10 | 14 |
| 208 | DKL18-70100D | 7.0 | 100 | 150 | 10 | 14 |

| NO. | Model Number | Balloon Nominal Diameter (mm) | Balloon Nominal Length (mm) | Catheter length (cm) | Balloon Nominal Pressure (atm) | Rated Burst Pressure (atm) |
|---|---|---|---|---|---|---|
| 209 | DKL18-70120D | 7.0 | 120 | 150 | 10 | 14 |
| 210 | DKL18-70150D | 7.0 | 150 | 150 | 10 | 14 |

The size of product is consisted with the serial, diameter of guidewire, nominal diameter of balloon, nominal length of balloon and length of catheter.

For example:

| **Model Number** | DKL | 18 | - | 70 | 20 | D |
|---|---|---|---|---|---|---|
| **Explanation** | series code | DOW | - | DOB | LOB | LOC |

Where

DKL: Represents the series code

DOW: Represents the diameter of guidewire, there is a total 2 options which is 18 and 14 and it represents the diameter of guidewire is 0.018inch and 0.014inch respectively.

DOB: Represents the nominal diameter of balloon, there is a total 10 options which is 25, 30, 35, 40, 45, 50, 55, 60, 65, 70 and it represents the nominal diameter of balloon is 2.5mm, 3.0mm, 3.5mm, 4.0mm, 4.5mm, 5.0mm, 5.5mm, 6.0mm, 6.5mm, 7.0mm respectively.

LOB: Represents the nominal length of balloon, there is a total 7 options which is 20, 40, 60, 80, 100, 120, 150 and it represents the nominal length of balloon is 20mm, 40mm, 60mm, 80mm, 100mm, 120mm, 150mm respectively.

LOC: Represents the length of catheter, there is a total 3 options which is B, C and D and it represents the length of catheter is 90cm, 135cm and 150cm respectively.

## INTENDED PURPOSE

To perform Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, using three scoring elements along the balloon length.

## INDICATIONS FOR USE

The Peripheral Scoring Balloon Dilatation Catheter is indicated for the treatment of obstructive lesions of the peripheral vasculature, including complex lesion morphologies.

## INTENDED USER

Physicians with adequate training in performance of percutaneous transluminal angioplasty.

## INTENDED PATIENT POPULATION

The intended population is adult patients who are eligible for Percutaneous Transluminal Angioplasty (PTA) procedure.

## CLINICAL BENEFIT

The use of the Peripheral Scoring Balloon Dilatation Catheter is to dilate stenotic lesions in the peripheral vasculature and improves blood perfusion.

## CONTRAINDICATIONS

- Use of the Peripheral Scoring Balloon Dilatation Catheter is contraindicated in situations where the Peripheral Scoring Balloon Dilatation Catheter would be passed through the struts of a previously placed stent as the deflated Peripheral Scoring Balloon Dilatation Catheter could become entangled in the stent.
- The Peripheral Scoring Balloon Dilatation Catheter is not for use in the coronary arteries and carotid arteries.
- The Peripheral Scoring Balloon Dilatation Catheter is not intended for the expansion or delivery of stents.

## WARNINGS

- Angioplasty with the Peripheral Scoring Balloon Dilatation Catheter, because of its mechanism of action, may pose a greater risk of perforation than that observed with conventional PTA. Oversizing increases the risk of perforation. To reduce the potential for vessel damage the inflated diameter of the Peripheral Scoring Balloon Dilatation Catheter should not exceed a 1.1:1 ratio of the diameter of the vessel just proximal and distal to the stenosis.
- Balloon pressure should not exceed the rated burst pressure. The rated burst pressure is based on the results of *in vitro* testing. At least 99.9% of the balloons (with a 95% confidence) will not burst at or below their rated burst pressure. Use of a pressure monitoring device is recommended to prevent over pressurization.
- Use only the recommended balloon inflation medium (e.g.- contrast medium). Never use air or any gaseous medium to inflate the balloon.
- Do not use in a kinked or buckled introducer sheath or if resistance is encountered. Resistance, kinking, or buckling in the introducer sheath may damage the scoring elements or balloon. If any of these occur, immediately withdraw both devices.
- When the catheter is exposed to the vascular system, it should be manipulated while under high-quality fluoroscopic observation. Do not advance or retract the catheter unless the balloon is fully deflated under vacuum. If resistance is met during manipulation, determine the cause of the resistance before proceeding.

## PRECAUTIONS

- Prior to angioplasty, the catheter should be examined to verify functionality and ensure that its size and shape are suitable for the specific procedure for which it is to be used.
- Only physicians who have received the appropriate training should use the Peripheral Scoring Balloon Dilatation Catheter.
- During the Peripheral Scoring Balloon Dilatation Catheter procedure, appropriate anticoagulant therapy should be provided to the patient. Anticoagulant therapy should be continued for a period of time after the procedure to be determined by the physician.
- The Peripheral Scoring Balloon Dilatation Catheter is not designed for, and therefore, cannot be used to monitor *in vivo* arterial pressures.

## POTENTIAL ADVERSE EVENTS

Risks associated with interventional treatment of stenosis with the Peripheral Scoring Balloon Dilatation Catheter are similar to those of conventional PTA. Potential risks include, but are not limited to:

- Allergic or drug reaction (device material, contrast medium and medications)

- Amputation
- Arteriovenous fistula
- Death
- Embolism
- Hematoma
- Hemorrhage
- Hypotension/hypertension
- Infection/Sepsis
- Ischemia/infarction of tissue/organ
- Pain
- Pseudoaneurysm
- Restenosis
- Surgical intervention
- Swelling
- Thrombosis
- Vascular occlusion
- Vessel injury (dissection, perforation, or rupture)
- Vessel spasm

## OPERATIONAL INSTRUCTIONS

### Preparation Technique

Prior to use, carefully examine the unit to verify that the catheter and sterile package have not been damaged in shipment.

Using sterile technique, remove the Peripheral Scoring Balloon Dilatation Catheter from its package and place onto the sterile field. Do not remove the catheter from its protective hoop at this time.

As supplied, the balloon lumen of the device contains air. This air must be displaced to make certain that only liquid fills the balloon while the catheter is in the bloodstream.

### To displace air

1. Connect a three-way stopcock to the balloon lumen. Turn the stopcock lever off to the balloon;
2. Fill a 20 ml (20 cc) syringe with approximately 4 ml (4 cc) of a mixture of contrast medium and normal saline;
3. Attach syringe to the three-way stopcock on the balloon lumen. Purge the stopcock by flushing the mixture of contrast medium and saline through the middle port;
4. Open the stopcock to the balloon. Draw back on the syringe to its full volume deflating the balloon and drawing air bubbles into the syringe barrel;
5. To make certain that all air is removed from the balloon, repeat step 4;
6. Close the stopcock to the balloon;
7. Remove the Peripheral Scoring Balloon Dilatation Catheter from its protective ring. Discard the protective hoop. Using straight force (not a twisting motion), pull the protective sheath off the balloon;
8. Flush the guidewire lumen of the Peripheral Scoring Balloon Dilatation Catheter with heparinized saline.

## Catheter Insertion

Introduce the Peripheral Scoring Balloon Dilatation Catheter percutaneously by Seldinger technique, using the 7Fr introducer sheath.

1. Insert a suitable guidewire through the Peripheral Scoring Balloon Dilatation Catheter guidewire lumen.
2. Gently grasp the proximal portion of the balloon at the shaft. Advance the Peripheral Scoring Balloon Dilatation Catheter through the introducer sheath, avoiding excessive pressure on the balloon as you advance it through the hemostasis valve to avoid unwanted contact with the scoring elements.
3. Under fluoroscopy, position the balloon so that the lesion is centered between the radiopaque markers on the balloon.

**Caution:** Do not advance the guidewire or the Peripheral Scoring Balloon Dilatation Catheter if the sheath is kinked, buckled or offers resistance.

## Balloon Inflation

Use an inflation device with a pressure gauge to monitor pressure within the balloon to determine that adequate dilatation force is applied while not exceeding the maximum limits of the product.

1. Under fluoroscopy, slowly inflate the Peripheral Scoring Balloon Dilatation Catheter 1 atm (101 kPa) every 5 seconds until. balloon indentation is no longer visible. Do not inflate the Peripheral Scoring Balloon Dilatation Catheter above 14 atm (1418 kPa). Hold inflation for 60 to 90 seconds. After dilating the lesion, slowly deflate the Peripheral Scoring Balloon Dilatation Catheter 1 atm (101 kPa) every 5 seconds.

**Caution:** Rapid deflation may compromise refold.

2. When using the on long lesion segments the distal portion(s) of the target lesion should be treated first. Then, overlapping dilation of the proximal lesion segment may be performed.

**Caution:** Optimal balloon refold depends upon many factors, including handling, vessel anatomy, lesion composition, inflation pressure, and number of inflations.

3. The standard inflation medium is a 1 :1 mixture of contrast medium and normal saline. Do not use air or any gaseous substances as a balloon inflation medium.
4. Do not exceed rated burst pressure of 14 atm (1418 kPa) during this process. Inflation in excess of rated burst pressure may cause the balloon to rupture. If loss of pressure within the balloon occurs during inflation or if balloon ruptures during dilation, immediately discontinue the procedure and deflate the balloon. Do not re-inflate; remove carefully.

**Caution:** The minimal dilating force required to dilate should be applied, minimizing risks of balloon over-inflation or rupture.

**Caution:** Appropriate sizing of the Peripheral Scoring Balloon Dilatation Catheter is extremely important. Do not exceed a balloon to vessel ratio of 1.1:1.

**Balloon Diameter to Inflation Pressures (Balloon Compliance)**

| Balloon Nominal Diameter (mm) | / | Pressure (atm) | | |
|---|---|---|---|---|
| | | (NP) 10 | 12 | (RBP) 14 |
| 2.5 | Balloon Diameter At Each Pressure | 2.50 | 2.54 | 2.57 |
| 3.0 | | 3.00 | 3.04 | 3.08 |
| 3.5 | | 3.50 | 3.55 | 3.60 |
| 4.0 | | 4.00 | 4.11 | 4.17 |

| Balloon Nominal Diameter (mm) | / (mm) | Pressure (atm) | | |
|---|---|---|---|---|
| | | (NP) 10 | 12 | (RBP) 14 |
| 4.5 | | 4.50 | 4.62 | 4.69 |
| 5.0 | | 5.00 | 5.18 | 5.26 |
| 5.5 | | 5.50 | 5.79 | 5.91 |
| 6.0 | | 6.00 | 6.19 | 6.27 |
| 6.5 | | 6.50 | 6.75 | 6.85 |
| 7.0 | | 7.00 | 7.21 | 7.29 |

NP: Nominal Pressure

RBP: Rated Burst Pressure

### Catheter Withdrawal

Deflate the Peripheral Scoring Balloon Dilatation Catheter by applying vacuum with the inflation/deflation device.

Maintain vacuum on the Peripheral Scoring Balloon Dilatation Catheter and verify deflation with fluoroscopy. Withdraw the Peripheral Scoring Balloon Dilatation Catheter from the lesion.

Repeat angiography to confirm successful result.

Withdraw the Peripheral Scoring Balloon Dilatation Catheter from the introducer sheath.

**Caution:** After removal from the introducer sheath, do not re-insert the Peripheral Scoring Balloon Dilatation Catheter.

**Caution:** If resistance is encountered when removing the catheter through an introducer sheath or a guidewire through the catheter, stop and remove them as a complete unit to prevent damage to the guidewire, catheter, introducer sheath, or vessel.

## HOW SUPPLIED

- Do not use if package is opened or damaged.
- Do not use if labeling is incomplete or illegible

The Peripheral Scoring Balloon Dilatation Catheter is supplied sterile and non-pyrogenic in an unopen, undamaged package. It is intended for single use only.

## STORAGE

Store in a cool, dry, dark place. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that products are used prior to the "Use By" date specified on the package label.

## STERILIZATION

EO Sterilization

## SHELF LIFE

36months

## DEVICE LIFETIME

The lifetime of the device comprises its shelf life, and the time the device is in use:

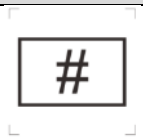
Shelf life: 36months

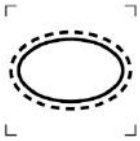
Time during which the device is in use: up to 1 hour.

## DISPOSAL INSTRUCTIONS

Dispose of the product and packaging in accordance with the policy of the hospital, administration, and/or local government.

## SYMBOLS AND EXPLANATION

| Symbol | Title | Symbol | Title |
|---|---|---|---|
|  | Model number |  | CE Marking |
|  | Manufacturer |  | Keep away from sunlight |
|  | Authorized representative in the European Community/European Union |  | Medical device |
|  | Date of manufacture |  | Keep dry |
|  | Use-by date |  | Temperature limit |
|  | Batch code |  | Fragile, handle with care |
|  | Do not re-use |  | Consult instructions for use or consult electronic instructions for use |

| Symbol | Title | Symbol | Title |
|---|---|---|---|
|   | Sterilized using ethylene oxide |  | Caution |
|   | Do not resterilize |  | Non-pyrogenic |
|  | Do not use if package is damaged and consult instructions for use |   | Unique device identifier |
|  | Single sterile barrier system with protective packaging outside |   | Contents |

## MANUFACTURER

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