

20th May 2021

URGENT: FIELD SAFETY NOTICE – PI-21-4000

Venovo™ Venous Stent System

REFs: Refer to Appendix 1

LOTS: All unexpired product

Type of Action: Product Removal

Attention: Venous Specialists, Clinical Personnel, Risk Managers, Biomedical Personnel

This letter contains important information which requires your attention.

Dear Customer,

BD is issuing this Field Safety Notice to remove all unexpired lots of **Venovo™ Venous Stent System** (Refer to Appendix 1 for Catalogue Numbers/REF's and Lot numbers shipped by BD to the EMEA market). Our distribution records indicate that your organisation may have received impacted devices.

Description of the Problem

BD has identified through customer feedback that the **Venovo™ Venous Stent System** has the potential to exhibit deployment issues whereby the proximal end of the stent may not immediately expand upon deployment. The proximal end of the stent instead remains connected to the stent cushion on the delivery system, as illustrated in Figure 1 below. Additional investigative studies of subject test samples have observed traces of cushion material (medical grade and biocompatible silicone) firmly adhered to the surface of the stent strut only where the stent cushion comes in contact with the stent.

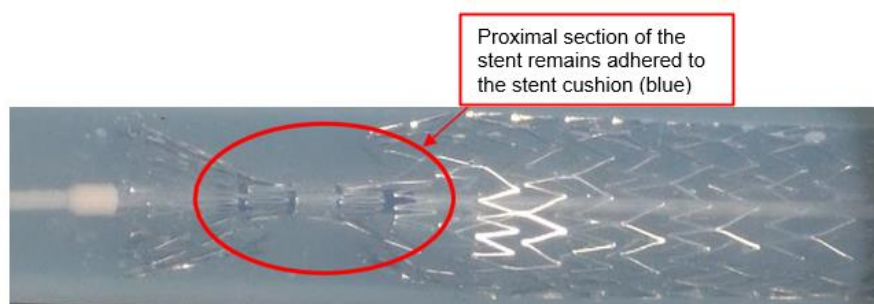
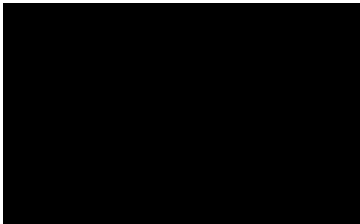


Figure 1: Proximal end of the stent remains connected to the stent cushion material.

Clinical Impact

In cases where the stent self-expands, there is no incremental risk of harm. Conversely, over-manipulation or forcing the catheter delivery system in attempts to assist the stent's expansion, could potentially have a varying degree of harm associated with it. Potential harm ranges from prolonging the procedure, damaging or deformity of the stent, potential vascular injury and / or hemodynamic disruption affecting the blood flow and / or a thrombotic event.

To date, BD has received complaints across various sizes of the product offering. The hazardous situation is that the stent, in a focal area near its proximal end, doesn't immediately expand at the time of deployment and the physician may not allow enough time for normal expansion, and tries to manipulate the stent or use other intravascular devices or techniques to help expand the stent. This may lead to misplacement or damage to the stent and vascular injury. A transfer of medical grade biocompatible silicone adhered to the inner surface of the



stent, if significant in size and detached, could lead to inflammatory responses or blockage/obstruction of the vasculature.

If the product has already been safely used, no patient follow-up activities are required. Please report any adverse health consequences experienced with the use of this product to BD if not already done so.

Corrective Actions by BD

BD has ceased manufacturing the product under scope of this Field Safety Notice and is conducting a detailed investigation into the root cause of the issue.

Advice on actions to be taken by the user

1. Please cease use of the **Venovo™ Venous Stent System**.
2. Identify, quarantine and destroy all lots of **Venovo™ Venous Stent System** (Refer to Attachment 1 for the Catalogue Numbers (REF) and Lot numbers)
 - a. All lots with an expiry date post April 2021 are in scope of this Product Removal (please refer to Appendix 2 to identify the expiry date on the product label)
3. Circulate this Field Safety Notice to all those within your organisation that may use the **Venovo™ Venous Stent System**.
4. If you have further distributed the product, please identify those users, and notify them at once of this Field Safety Notice.
5. Return the completed Customer Acknowledgment (Reply) Form on page 3 to <<email>> **as soon as possible or no later than June 30th, 2021**.
 - a. NOTE: If you no longer use the product, it is still important that you return the Customer Response Form for our reconciliation purposes.
 - b. NOTE: BD will issue credit for all customers affected by the recall following receipt of the completed Customer Response Form.

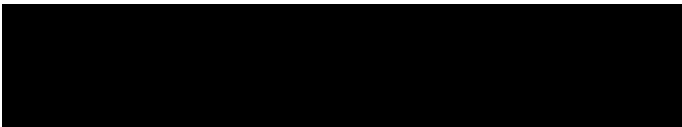
Should you have any questions or experience any issues associated with the product or issue described in this Field Safety Notice, please contact your local BD representative.

We confirm that the appropriate regulatory agencies have been informed of these actions.

BD is committed to ensuring that safe and effective product is available to customers and this Field Safety Notice is taken with due consideration of this commitment.

Thank you for your attention and cooperation.

Yours sincerely,





Customer Acknowledgement Form – PI-21-4000

Venovo™ Venous Stent System

Please read in conjunction with Field Safety Notice, PI-21-4000 and return the completed and signed form as soon as possible or **no later than June 30th, 2021** to <<email>>

By signing below, you confirm this notice has been read, understood and that all recommended actions have been implemented as required.

Tick the appropriate box below:

We do not have any of the affected product in our possession.

OR

We have units of the affected product and confirm that the following number of units listed below have been destroyed (***please attach additional lists as required***)

| Catalogue Number (REF) | Lot Number | Quantity Destroyed (units) | | Catalogue Number (REF) | Lot Number | Quantity Destroyed (units) |
|------------------------|------------|----------------------------|--|------------------------|------------|----------------------------|
| | | | | | | |
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| | | | |
|--|--|-----------------------|--|
| Name of Trust / Organisation | | | |
| Your Facility Address | | | |
| Postcode | | | |
| Telephone number | | E-mail address | |
| Name of your supplier for this product <i>(if not direct from BD)</i> | | | |

| Please list <u>all</u> Facilities / Hospitals covered by your response <i>(e.g. other hospitals within your Trust)</i> | Facility / Hospital Name | Postcode |
|--|--------------------------|----------|
| | | |
| | | |
| | | |

| | | | |
|------------------|--|------------------|--|
| Your Name | | Job Title | |
| Signature | | Date | |

Appendix 1: Impacted Venovo™ Stent System - EMEA Catalogue Number (REF) & Lot Numbers

| Catalogue Number (REF) | Product Name, Sheath Size, Stent Diameter x Length, Catheter Length | Unique Device Identifier (UDI-DI) | Lot Numbers |
|------------------------|---|-----------------------------------|--|
| VENEM10040 | Venovo 8F 10/40/800mm OUS | 00801741101939 | ANDU2240, ANDY3304, ANDZ2288, ANDZ3827, ANEP2429, ANEP5328, ANES1042, ANES2208, ANEY3214, ANEY4323, ANFP2666 |
| VENEM10060 | Venovo 8F 10/60/800mm OUS | 00801741101946 | ANDU1102, ANDV1222, ANDV2517, ANDX5352, ANDY2458, ANDY3301, ANDZ1338, ANDZ3819, ANEN1079, ANEN3405, ANEQ4065, ANEQ4961, ANER5167, ANEX0679, ANEX4720, ANEY4324, ANEZ0921, ANEZ2095, ANEZ3410, ANFN3972, ANFP2325 |
| VENEM10080 | Venovo 8F 10/80/800mm OUS | 00801741101953 | ANDU1105, ANDV0287, ANDW4412, ANDX0715, ANDX5308, ANDZ1330, ANDZ2292, ANDZ3826, ANEN1080, ANEQ2730, ANEQ4066, ANES2209, ANET2531, ANEX1699, ANEY3212, ANEY4325, ANEZ0982, ANFP0878, ANFP2364 |
| VENEM10100 | Venovo 8F 10/100/800mm OUS | 00801741101960 | ANDY3305, ANEP0856, ANEP5323, ANEQ2731, ANEQ4067, ANER0516, ANES2210, ANEZ0922, ANFN1442, ANFN3973 |
| VENEM10120 | Venovo 8F 10/120/800mm OUS | 00801741101977 | ANDT1058, ANDU4075, ANDZ1348, ANEN1081, ANEP0857, ANEP3924, ANEQ4068, ANET3794, ANEX0680, ANEZ2096, ANFP2329 |
| VENEM10140 | Venovo 8F 10/140/800mm OUS | 00801741101984 | ANDZ2290, ANEP5324 |
| VENEM10160 | Venovo 8F 10/160/800mm OUS | 00801741101991 | ANDZ2296, ANEP5332, ANFP2330 |
| VENEM12040 | Venovo 8F 12/40/800mm OUS | 00801741102073 | ANDS4772, ANDT0508, ANDW4345, ANDX5315, ANDX5384, ANDY4968, ANDZ2301, ANDZ3817, ANEN4877, ANEP0861, ANEQ2732, ANER5152, ANET0555, ANET3795, ANEW3410, ANEY1223, ANEZ2097, ANEZ3411, ANFN1443, ANFN3974, ANFP0911, ANFP2377 |
| VENEM12060 | Venovo 8F 12/60/800mm OUS | 00801741102080 | ANDS2451, ANDS3973, ANDS4774, ANDT2946, ANDU1877, ANDV0687, ANDW1997, ANDW3561, ANDW4361, ANDX0760, ANDX2782, ANDX3060, ANDX5373, ANDY1234, ANDZ2291, ANDZ3820, ANEN1082, ANEN2140, ANEN4896, ANEP2420, ANEQ1353, ANEQ2733, ANEQ4962, ANER0517, ANER1507, ANES1043, ANES2211, ANES4086, ANEZ0923, ANEZ2098, ANEZ3412, ANFN1444, ANFN2844, ANFN3975, ANFP0879, ANFP2317, ANFP2318 |
| VENEM12080 | Venovo 8F 12/80/800mm OUS | 00801741102097 | ANDS0753, ANDT4130, ANDU3110, ANDV0300, ANDV0702, ANDV1233, ANDV2519, ANDW4378, ANDX0727, ANDX2032, ANDX2426, ANDX3063, ANDX5307, ANDY1221, ANDY2464, ANDY3291, |

| Catalogue Number (REF) | Product Name, Sheath Size, Stent Diameter x Length, Catheter Length | Unique Device Identifier (UDI-DI) | Lot Numbers |
|------------------------|---|-----------------------------------|--|
| | | | ANDZ1331, ANDZ2297, ANDZ3824, ANEN1064, ANEN2145, ANEN3389, ANEN4886, ANEP0860, ANEP3934, ANEQ1354, ANEQ4069, ANER5168, ANES2212, ANEZ0924, ANEZ2099, ANEZ3952, ANFN2787, ANFN3976, ANFP0912, ANFP2336 |
| VENEM12100 | Venovo 8F 12/100/800mm OUS | 00801741102103 | ANDS2461, ANDS3976, ANDS4839, ANDT4131, ANDU1889, ANDW1999, ANDW4395, ANDX0739, ANDX2031, ANDX3062, ANDX5323, ANDX5363, ANDY1231, ANDY3284, ANDY4974, ANDZ3823, ANEN2147, ANEN3398, ANEQ1355, ANEQ2734, ANEQ4963, ANER0475, ANER0518, ANER1508, ANES4087, ANET0556, ANEY2031, ANEZ2100, ANEZ3429, ANFN1445, ANFN3977, ANFP2365 |
| VENEM12120 | Venovo 8F 12/120/800mm OUS | 00801741102110 | ANDU4028, ANDV0275, ANDW4413, ANDX0751, ANDX5301, ANDY4972, ANEN1083, ANEN4883, ANEP5329, ANEQ2735, ANER5120, ANES4088, ANFP0880, ANFP2331 |
| VENEM12140 | Venovo 8F 12/140/800mm OUS | 00801741102127 | ANDU1103, ANDU4040, ANDX5327, ANDX5389, ANDZ1326, ANEP5309, ANEQ1356, ANEQ2736, ANER0519, ANER1535 |
| VENEM12160 | Venovo 8F 12/160/800mm OUS | 00801741102134 | ANDU1104, ANDY2452, ANDY3299, ANDZ3825, ANEN1084, ANEN4894, ANEQ4964, ANER0520 |
| VENEM14040 | Venovo 9F 14/40/800mm OUS | 00801741102226 | ANDS1298, ANDS4185, ANDV4538, ANDW2003, ANDW3567, ANDX0765, ANDX2427, ANDX3065, ANDX5353, ANDY1226, ANDZ2279, ANDZ3828, ANEN1065, ANEN2142, ANEN3391, ANEQ1357, ANEQ2737, ANEQ4070, ANEQ4965, ANES1029, ANES4089, ANEX1705, ANEY2032, ANEY3213, ANEZ0985, ANEZ3425, ANFN1494, ANFN2845, ANFP0913, ANFP2378, ANFQ2056 |
| VENEM14060 | Venovo 9F 14/60/800mm OUS | 00801741102233 | ANDS1311, ANDS4773, ANDS4840, ANDV0709, ANDW3559, ANDX0711, ANDX2029, ANDX3059, ANDX5372, ANDY1218, ANDY4958, ANDZ1324, ANDZ2275, ANDZ3838, ANEN3392, ANEN4876, ANEP0871, ANEP2432, ANEP3925, ANEQ0218, ANEQ1358, ANEQ2738, ANEQ4753, ANEQ4966, ANER0528, ANES1044, ANES2213, ANEZ0925, ANEZ2101, ANEZ3413, ANEZ3932, ANFN1446, ANFN2788, ANFN3978, ANFP0881, ANFP2354, ANFQ2082, ANFQ2925 |
| VENEM14080 | Venovo 9F 14/80/800mm OUS | 00801741102240 | ANDS2470, ANDS3974, ANDS4775, ANDT1680, ANDU3123, ANDV3568, ANDV4535, ANDW1478, ANDW3563, ANDX1479, ANDX3061, ANDY1237, ANDY2449, ANDY3282, ANDZ1325, ANDZ2282, ANDZ3821, ANEN1062, ANEN3390, ANEN4871, ANEP2434, ANEQ0215, ANEQ1359, ANEQ4967, |

| Catalogue Number (REF) | Product Name, Sheath Size, Stent Diameter x Length, Catheter Length | Unique Device Identifier (UDI-DI) | Lot Numbers |
|------------------------|---|-----------------------------------|--|
| | | | ANER0521, ANER1509, ANES1045, ANES2214, ANES4090, ANEW3418, ANEZ0926, ANEZ2102, ANEZ3414, ANEZ3933, ANFN2789, ANFN3979, ANFN3980, ANFP2366, ANFQ1012 |
| VENEM14100 | Venovo 9F 14/100/800mm OUS | 00801741102257 | ANDS0754, ANDS3977, ANDS4778, ANDT1681, ANDV0706, ANDV4537, ANDW2000, ANDW3565, ANDW4347, ANDX0723, ANDX2033, ANDX3064, ANDX5300, ANDX5382, ANDY1212, ANDY4957, ANDZ1329, ANDZ2284, ANDZ3837, ANEN2136, ANEN3400, ANEN4879, ANEP0870, ANEP2426, ANEQ1360, ANEQ2739, ANEQ4968, ANER0529, ANER1536, ANES1030, ANET0557, ANEY2033, ANEZ0927, ANEZ2103, ANEZ3415, ANEZ3934, ANFN1447, ANFN2790, ANFN3981, ANFP0882, ANFP2355 |
| VENEM14120 | Venovo 9F 14/120/800mm OUS | 00801741102264 | ANDS2482, ANDT4128, ANDU1113, ANDW4362, ANDX0716, ANDX3058, ANDX5314, ANDY1213, ANDY2460, ANDZ1323, ANDZ2281, ANDZ3816, ANEN2149, ANEN4884, ANEP2415, ANEQ1361, ANEQ2740, ANEQ4071, ANER1534, ANES2215, ANEZ0928, ANEZ3416, ANFN2791, ANFN3982, ANFP2379 |
| VENEM14140 | Venovo 9F14/140/800mm OUS | 00801741102271 | ANDS2452, ANDS3975, ANDS4777, ANDT4129, ANDW4379, ANDX5322, ANDX5383, ANDZ1354, ANDZ3822, ANEN2155, ANEP0872, ANEQ2741, ANEQ4072, ANER0522, ANES2216, ANET0558, ANEZ3428, ANFP2332, ANFQ2057 |
| VENEM14160 | Venovo 9F 14/160/800mm OUS | 00801741102288 | ANDU1107, ANDU1900, ANDU3137, ANDW4396, ANDY2461, ANDY3277, ANDY4969, ANDZ1321, ANEP0853, ANEP5311, ANEQ1362, ANEQ2742, ANER0523, ANER2794, ANES4091, ANET3796, ANEZ2104, ANEZ3423, ANFP2333 |
| VENEM16040 | Venovo 10F 16/40/800mm OUS | 00801741102363 | ANDS3980, ANDV0265, ANDV2520, ANDW4415, ANDX5306, ANDY2465, ANDY3303, ANDZ1339, ANDZ3832, ANEN3393, ANEP2433, ANEQ1363, ANEQ2743, ANEQ4969, ANES1031, ANEW3409, ANEX0752, ANEX6159, ANEZ0929, ANEZ3417, ANFN2849, ANFP0883, ANFP2367, ANFQ2058 |
| VENEM16060 | Venovo 10F 16/60/800mm OUS | 00801741102370 | ANDS1325, ANDS3979, ANDS4783, ANDT1684, ANDT2944, ANDV0252, ANDV0708, ANDV1247, ANDV1984, ANDV2513, ANDW4348, ANDX0755, ANDX2037, ANDX2423, ANDX3070, ANDX5326, ANDX5388, ANDY1215, ANDZ1355, ANDZ3831, ANEN1066, ANEN2135, ANEN4887, ANEP2422, ANEP3928, ANEQ1364, ANEQ2744, ANER1539, ANES1046, ANES2217, ANES4092, ANEW3411, ANEX0751, ANEZ0930, ANEZ2105, ANEZ3418, |

| Catalogue Number (REF) | Product Name, Sheath Size, Stent Diameter x Length, Catheter Length | Unique Device Identifier (UDI-DI) | Lot Numbers |
|------------------------|---|-----------------------------------|--|
| | | | ANFN1448, ANFN2792, ANFN3983, ANFP0884, ANFP2356, ANFP3400, ANFP4500 |
| VENEM16080 | Venovo 10F 16/80/800mm OUS | 00801741102387 | ANDS0760, ANDS1272, ANDS3981, ANDS4784, ANDT1685, ANDV0694, ANDV3571, ANDV4540, ANDW1485, ANDW2016, ANDW3579, ANDW4364, ANDX0707, ANDX2041, ANDX2424, ANDX3074, ANDX5318, ANDY1224, ANDZ1341, ANDZ2289, ANDZ3833, ANEN1067, ANEN2137, ANEN4874, ANEP0869, ANEP2431, ANEP3940, ANEQ1365, ANEQ2745, ANER1542, ANES1032, ANES4093, ANEV3070, ANEW2004, ANEW3377, ANEX6015, ANEZ0931, ANEZ3419, ANEZ3937, ANFN1495, ANFN2793, ANFN3984, ANFP0885, ANFP2339, ANFP3403 |
| VENEM16100 | Venovo 10F 16/100/800mm OUS | 00801741102394 | ANDU1855, ANDU3138, ANDV4530, ANDW4381, ANDX0735, ANDX3067, ANDX5325, ANDX5386, ANDY3294, ANDZ1334, ANDZ3830, ANEN1061, ANEN3388, ANEN4882, ANEP2416, ANEP3926, ANEQ1366, ANEQ2746, ANES1047, ANEZ3433, ANEZ3938, ANFN2847, ANFP0886, ANFP2380, ANFP4501 |
| VENEM16120 | Venovo 10F 16/120/800mm OUS | 00801741102400 | ANDV0713, ANDW1481, ANDW2008, ANDX0747, ANDX5365, ANDY2453, ANDY3279, ANEN3383, ANEN4885, ANEQ1367, ANEQ2747, ANEQ4073, ANEQ4970, ANER1525, ANES2218, ANES4094, ANET0559, ANEX3089, ANEY4326, ANEZ0983, ANEZ3420, ANFN1449, ANFN3985, ANFP0887, ANFP2334, ANFP3397 |
| VENEM16140 | Venovo 10F 16/140/800mm OUS | 00801741102417 | ANDS2462, ANDS4841, ANDX2786, ANDX5371, ANDZ3836, ANEN4891, ANEP3913, ANEP5312, ANEQ1374, ANER1547, ANFQ1013 |
| VENEM16160 | Venovo 10F 16/160/800mm OUS | 00801741102424 | ANDU4050, ANDV0695, ANDV1258, ANDX0728, ANDX5366, ANDY2454, ANDY3300, ANEN1068, ANEN4878, ANEP0858, ANEP2410, ANEP3915, ANEP5313, ANEQ4971, ANER0524, ANER1510, ANES2219, ANES4095, ANFN1450, ANFQ1014 |
| VENEM18040 | Venovo 10F 18/40/800mm OUS | 00801741102509 | ANDT1056, ANDW4398, ANDX5360, ANDZ1349, ANDZ2302, ANEN4890, ANEP3917, ANEP5321, ANEQ4074, ANER1526, ANEW4261, ANEZ3421, ANFP3414 |
| VENEM18060 | Venovo 10F 18/60/800mm OUS | 00801741102516 | ANDS4787, ANDU4073, ANDV0700, ANDV1211, ANDV2136, ANDV2518, ANDX0761, ANDX5350, ANDZ1351, ANDZ2280, ANEN2143, ANEN3394, ANEN4875, ANEP2411, ANEQ1368, ANEQ2748, ANEQ4972, ANER1546, ANES1033, ANEZ0984, ANFN1451, ANFN3986, ANFP0888, ANFP0889, ANFP2335, ANFP3413 |

| Catalogue Number (REF) | Product Name, Sheath Size, Stent Diameter x Length, Catheter Length | Unique Device Identifier (UDI-DI) | Lot Numbers |
|------------------------|---|-----------------------------------|--|
| VENEM18080 | Venovo 10F 18/80/800mm OUS | 00801741102523 | ANDS2471, ANDS4781, ANDV0696, ANDW1483, ANDW2011, ANDW4416, ANDX0719, ANDX3068, ANDX5328, ANDX5368, ANDY1233, ANDZ1356, ANEN2138, ANEP2425, ANEP3916, ANEQ1369, ANEQ2749, ANEQ4973, ANER0525, ANER1538, ANES1048, ANES2220, ANET0560, ANEZ0932, ANEZ2106, ANEZ3422, ANFN1452, ANFN3987, ANFP0890, ANFP2342 |
| VENEM18100 | Venovo 10F 18/100/800mm OUS | 00801741102530 | ANDU4076, ANDW1479, ANDW2006, ANDX0712, ANDX2785, ANDX5364, ANDY1232, ANDZ2299, ANEN2154, ANEN3381, ANEP2437, ANEP3914, ANEP5316, ANEQ1370, ANEQ2750, ANER0476, ANER0526, ANER1511, ANES1049, ANES4096, ANFP3415, ANFQ1015 |
| VENEM18120 | Venovo 10F 18/120/800mm OUS | 00801741102547 | ANDW2022, ANDW4350, ANDY3278, ANEN1069, ANEN3401, ANEP2419, ANFP2343 |
| VENEM18140 | Venovo 10F 18/140/800mm OUS | 00801741102554 | ANDW2025, ANDX0740, ANDY2466, ANDY3281, ANEN1085, ANEP0873, ANEP5314, ANEQ1371, ANEQ2751, ANEQ4974, ANER0527, ANER1512, ANES4097 |
| VENEM18160 | Venovo 10F 18/160/800mm OUS | 00801741102561 | ANDX0752, ANDX5380, ANDY3307, ANEN4889, ANEQ4075, ANFN1453 |
| VENEM20040 | Venovo 10F 20/40/800mm OUS | 00801741102998 | ANDV0697, ANDY2451, ANDY4970, ANDZ1344, ANEP3921, ANEQ4076, ANEQ4975, ANER0507, ANES4098, ANEZ0933, ANFP0914, ANFP4502 |
| VENEM20060 | Venovo 10F 20/60/800mm OUS | 00801741103001 | ANDV4532, ANDW2026, ANDX0766, ANDX2783, ANDX5370, ANDZ1350, ANDZ2303, ANEN3384, ANEP2440, ANEP3918, ANEP5330, ANEQ1372, ANEQ2752, ANEQ4976, ANER0508, ANER0509, ANES4099, ANFP3412, ANFP4503 |
| VENEM20080 | Venovo 10F 20/80/800mm OUS | 00801741103018 | ANDV4527, ANDW4366, ANDX0724, ANDX5351, ANDY2468, ANDY3292, ANDZ1333, ANDZ2277, ANEP2439, ANEP3933, ANEQ1373, ANEQ2753, ANEQ4077, ANEQ4977, ANER0506, ANER1513, ANES4100, ANFP2344 |
| VENEM20100 | Venovo 10F 20/100/800mm OUS | 00801741103025 | ANDW1490, ANDW2027, ANDY2455, ANDY3285, ANEP0874, ANEP5310, ANER1527, ANES4101, ANET2532, ANEU0743 |
| VENEM20120 | Venovo 10F 20/120/800mm OUS | 00801741103032 | ANDW2024, ANDZ2294, ANEP0876, ANEP5331, ANES2221 |
| VENEM20140 | Venovo 10F 20/140/800mm OUS | 00801741103049 | ANDU4029, ANDY2450, ANDY3296, ANEN3399, ANEN4870, ANEP2438, ANFP2345, VENEM20160 |

| Catalogue Number (REF) | Product Name, Sheath Size, Stent Diameter x Length, Catheter Length | Unique Device Identifier (UDI-DI) | Lot Numbers |
|------------------------|---|-----------------------------------|--|
| VENEM20160 | Venovo 10F 20/160/800mm OUS | 00801741103056 | ANDV0253, ANDW2005, ANEP0875, ANEP5315, ANEQ2754, ANES2222, ANFN3988 |
| VENEL10040 | Venovo 8F 10/40/1200mm OUS | 00801741102004 | ANDU2239, ANDW4406, ANDX5374, ANEP3938, ANEQ2716, ANES2187 |
| VENEL10060 | Venovo 8F 10/60/1200mm OUS | 00801741104664 | ANDT1057, ANDU4074, ANDW4338, ANDX5309, ANDZ2308, ANEP0852, ANEP3936, ANEQ4036, ANEQ4945, ANER5149, ANET3785, ANEX0671, ANEX3092, ANEZ0906, ANEZ3430, ANFN1430, ANFP2368 |
| VENEL10080 | Venovo 8F 10/80/1200mm OUS | 00801741104671 | ANDU4027, ANDV4526, ANDW4339, ANDX5324, ANDX5385, ANDZ3818, ANEN1086, ANEQ2717, ANEQ4037, ANEQ4946, ANER5165, ANET2530, ANEU0741, ANEU3303, ANEX0749, ANEZ0907, ANFN3944, ANFP2369 |
| VENEL10100 | Venovo 8F 10/100/1200mm OUS | 00801741102035 | ANDT0505, ANDT1054, ANDY2469, ANDY4963, ANDZ1345, ANEP0862, ANEP2417, ANEW2047, ANEW4217, ANEY3209, ANEY4322, ANFN1431, ANFN3945, ANFP2370 |
| VENEL10120 | Venovo 8F 10/120/1200mm OUS | 00801741102042 | ANEQ1347, ANES2188, ANFP2349 |
| VENEL10140 | Venovo 8F 10/140/1200mm OUS | 00801741102059 | ANDU1108, ANDY3280, ANEN3385, ANEQ1348, ANEQ4038 |
| VENEL10160 | Venovo 8F10/160/1200mm OUS | 00801741102066 | ANDS1027, ANDW1996, ANDX6354, ANDY2448, ANET1855 |
| VENEL12040 | Venovo 8F 12/40/1200mm OUS | 00801741102141 | ANDT0506, ANDT1055, ANDU2242, ANDU4039, ANDW1998, ANDX1402, ANDY3289, ANDY4964, ANDZ2307, ANEN2153, ANEP2424, ANES2189, ANET0542, ANEW3366, ANEW4218, ANEX1697, ANEX6010, ANEZ0908, ANEZ2081, ANEZ3398, ANFN3946, ANFP0857, ANFP2319 |
| VENEL12060 | Venovo 8F 12/60/1200mm OUS | 00801741102158 | ANDS0752, ANDT0507, ANDT1059, ANDV4534, ANDX1401, ANDX2425, ANDX3057, ANDX5362, ANDY1230, ANDZ1322, ANDZ2286, ANEN4897, ANEP0867, ANEP2421, ANEP3930, ANEQ2718, ANEQ4039, ANER1514, ANES2190, ANES4062, ANEV1711, ANEW3367, ANEW4219, ANEX0746, ANEX1708, ANEX3091, ANEX6018, ANEY1228, ANEZ2082, ANFN1432, ANFN3947, ANFP0858, ANFP2358, ANFP4499 |
| VENEL12080 | Venovo 8F 12/80/1200mm OUS | 00801741102172 | ANDV3567, ANDV4528, ANDX1374, ANDX1405, ANDX2034, ANDY1238, ANDY4960, ANDZ1332, ANDZ2304, ANEN1070, ANEN3402, ANEP3939, ANEP5317, ANEQ2719, ANEQ4040, ANER5118, ANES2191, ANET0543, ANET3786, ANEW4260, |

| Catalogue Number (REF) | Product Name, Sheath Size, Stent Diameter x Length, Catheter Length | Unique Device Identifier (UDI-DI) | Lot Numbers |
|------------------------|---|-----------------------------------|--|
| | | | ANEX3093, ANEX6157, ANEY1221, ANEY2034, ANEY3210, ANEZ3431, ANFN2783, ANFN3948, ANFP0859, ANFP2359 |
| VENEL12100 | Venovo 8F 12/100/1200mm OUS | 00801741102189 | ANDU2243, ANDV1244, ANDW4355, ANDX1406, ANDX2035, ANDX5316, ANDX5390, ANDY3308, ANDZ2283, ANEN1071, ANEN4895, ANEP2435, ANEQ2720, ANEQ4041, ANEQ4947, ANER1515, ANES4063, ANET3787, ANEW3412, ANEX0672, ANEX3081, ANEX6011, ANEY3211, ANEZ3399, ANFN1433, ANFN3949, ANFP0908, ANFP2360, ANFP3394 |
| VENEL12120 | Venovo 8F 12/120/1200mm OUS | 00801741102196 | ANDS0751, ANDS4788, ANDS4823, ANDU2244, ANDV4533, ANDW4372, ANDX1373, ANDX3056, ANDX5361, ANDY1229, ANDY2456, ANDY3283, ANDY4965, ANDZ1327, ANDZ2287, ANEN2150, ANEN4880, ANEP0877, ANEQ4042, ANER1516, ANEW4220, ANEX1707, ANFN1434, ANFN2784, ANFN3950, ANFN3951, ANFP2361 |
| VENEL12140 | Venovo 8F 12/140/1200mm OUS | 00801741102202 | ANDS1282, ANDU2245, ANDW2002, ANDW4389, ANDX5376, ANDY3288, ANEN1072, ANEN3387, ANEP2430, ANEQ4043, ANER1517, ANES4064, ANFN3952, ANFN3953, ANFP0860 |
| VENEL12160 | Venovo 8F 12/160/1200mm OUS | 00801741102219 | ANDS4776, ANDT1686, ANDV4536, ANDX1403, ANDX5375, ANDY3287, ANEP2412, ANEQ4948, ANES4065, ANEZ3427, ANFN3954, ANFP0861 |
| VENEL14040 | Venovo 9F 14/40/1200mm OUS | 00801741102295 | ANDS0902, ANDS1029, ANDS4184, ANDT2943, ANDU1106, ANDV0250, ANDV1245, ANDV2515, ANDW2001, ANDW4407, ANDX1404, ANDX6356, ANDY4962, ANEP3937, ANEQ4044, ANEQ4949, ANER0505, ANES1035, ANES4066, ANET1856, ANET1857, ANEW3368, ANEW4221, ANEX6012, ANEZ0909, ANEZ2083, ANEZ3424, ANFN1435, ANFN2785, ANFP0862, ANFP2362, ANFP3393 |
| VENEL14060 | Venovo 9F 14/60/1200mm OUS | 00801741102301 | ANDS0757, ANDS1269, ANDS2479, ANDS4824, ANDT2945, ANDU2246, ANDV0251, ANDV0690, ANDV1256, ANDX0759, ANDX2039, ANDX3072, ANDX5305, ANDY1220, ANEN1073, ANEN2152, ANEP0854, ANEP3569, ANEP3931, ANES2192, ANES4067, ANET0544, ANEU4252, ANEW2002, ANEW3369, ANEW4222, ANEX0673, ANEX1702, ANEX3082, ANEX4716, ANEX6023, ANEY1224, ANEZ0910, ANEZ2084, ANEZ3400, ANFN3955, ANFP0863, ANFP2320, ANFP3402 |
| VENEL14080 | Venovo 9F 14/80/1200mm OUS | 00801741102318 | ANDS0756, ANDS1283, ANDS4825, ANDW4341, ANDX1380, ANDX1412, ANDX2038, ANDX3071, ANDX5311, ANDY1222, ANDY2462, ANDY4973, |

| Catalogue Number (REF) | Product Name, Sheath Size, Stent Diameter x Length, Catheter Length | Unique Device Identifier (UDI-DI) | Lot Numbers |
|------------------------|---|-----------------------------------|--|
| | | | ANDZ1352, ANDZ3839, ANEN2144, ANEN3396, ANEP3935, ANEP5326, ANEQ4045, ANEQ4950, ANER1540, ANES2193, ANES4068, ANET0545, ANET3788, ANEW2046, ANEW3416, ANEX0674, ANEX1700, ANEX3083, ANEX6022, ANEY1225, ANEY4328, ANEZ0911, ANEZ2085, ANEZ3401, ANEZ3957, ANFN2848, ANFN3956, ANFP0864, ANFP1519, ANFP2315, ANFP2316 |
| VENEL14100 | Venovo 9F 14/100/1200mm OUS | 00801741102325 | ANDS1296, ANDS4826, ANDT1683, ANDV0711, ANDV1209, ANDV3569, ANDW1480, ANDX1408, ANDX2036, ANDX5302, ANDY3309, ANDZ1342, ANDZ2276, ANDZ3829, ANEN1074, ANEN4899, ANEP0866, ANEP3927, ANEP5325, ANEQ4046, ANEQ4951, ANER1537, ANES2194, ANES4069, ANET0546, ANET3789, ANEV1712, ANEW2003, ANEW3370, ANEW4223, ANEX0747, ANEX1709, ANEX3094, ANEX6019, ANEZ0912, ANEZ2086, ANEZ3402, ANEZ3956, ANFN2846, ANFN3957, ANFP0865, ANFP2340, ANFP3395 |
| VENEL14120 | Venovo 9F 14/120/1200mm OUS | 00801741102332 | ANDS1310, ANDS4827, ANDV0698, ANDV3572, ANDV4541, ANDW1486, ANDX1382, ANDX1416, ANDX3075, ANDX5319, ANDY1225, ANDY3298, ANDZ2278, ANDZ3834, ANEN1075, ANEP0878, ANEP2428, ANEP3932, ANEQ2721, ANEQ4047, ANEQ4952, ANER1543, ANES2195, ANES4070, ANET0547, ANEW3421, ANEX0754, ANEZ0913, ANEZ2087, ANEZ3403, ANFN2850, ANFN3958, ANFN3959, ANFP0866, ANFP2337, ANFP3405 |
| VENEL14140 | Venovo 9F 14/140/1200mm OUS | 00801741102349 | ANDU2247, ANDU3135, ANDV0710, ANDV2510, ANDV3575, ANDW4356, ANDX1372, ANDX1386, ANDX3079, ANDY1219, ANDY2463, ANDY4971, ANDZ3835, ANEN3397, ANEP3919, ANEQ2722, ANEQ4048, ANEQ4953, ANES2196, ANET0548, ANEX1704, ANEY1222, ANEY2035, ANEZ2088, ANEZ3438, ANFN3960, ANFN3961, ANFP0867, ANFP2363, ANFP3410 |
| VENEL14160 | Venovo 9F 14/160/1200mm OUS | 00801741102356 | ANDS0761, ANDS3982, ANDS4785, ANDS4828, ANDU2248, ANDU3096, ANDV0298, ANDV1221, ANDV2511, ANDW1487, ANDX1418, ANDX2042, ANDX3077, ANDX5320, ANDY1216, ANEN2139, ANEP0868, ANEQ0214, ANEQ1349, ANER1545, ANES4071, ANEZ0914, ANEZ2089, ANEZ3437, ANFN3962, ANFP0868, ANFP2341, ANFP3407 |
| VENEL16040 | Venovo 10F 16/40/1200mm OUS | 00801741102431 | ANDS4829, ANDU1854, ANDU3109, ANDX5303, ANDY3290, ANDY4966, ANEN1076, ANEN3916, ANEP3923, ANEQ2723, ANEQ4049, ANEQ4954, ANER5134, ANES4072, ANEW4224, ANEX3084, ANEX6013, ANEY2036, ANEZ3432, ANFP0909, ANFP2371 |

| Catalogue Number (REF) | Product Name, Sheath Size, Stent Diameter x Length, Catheter Length | Unique Device Identifier (UDI-DI) | Lot Numbers |
|------------------------|---|-----------------------------------|--|
| VENEL16060 | Venovo 10F 16/60/1200mm OUS | 00801741102448 | ANDS4830, ANDT1060, ANDT1682, ANDU3122, ANDU4071, ANDV0703, ANDW4373, ANDX1375, ANDX1407, ANDX2422, ANDX3066, ANDX5321, ANDY1227, ANDZ1336, ANDZ2305, ANEN1077, ANEN2141, ANEN4898, ANEP0855, ANEP2413, ANEQ4050, ANEQ4955, ANER0473, ANER1518, ANES2197, ANES4073, ANET0549, ANEW4225, ANEX0675, ANEX1701, ANEX3085, ANEY2028, ANEZ0915, ANEZ2090, ANEZ3404, ANFN1436, ANFN2786, ANFP0869, ANFP2326 |
| VENEL16080 | Venovo 10F 16/80/1200mm OUS | 00801741102455 | ANDU1111, ANDU3136, ANDV0286, ANDV0707, ANDV2514, ANDW4390, ANDX1417, ANDX2784, ANDX3076, ANDX5379, ANDY1235, ANDY2457, ANDY4959, ANDZ1346, ANDZ2285, ANDZ3840, ANEN3403, ANEN4900, ANEP0864, ANEP3566, ANEP3941, ANEQ4051, ANEQ4956, ANER1544, ANES2198, ANES4074, ANET0550, ANET3790, ANEW3371, ANEW4226, ANEX0676, ANEX3086, ANEX4717, ANEX6014, ANEY1226, ANEY4327, ANEZ3405, ANFN1437, ANFN3963, ANFP0870, ANFP2338 |
| VENEL16100 | Venovo 10F 16/100/1200mm OUS | 00801741102462 | ANDS1323, ANDS2480, ANDS4831, ANDT1229, ANDV0691, ANDX0750, ANDX1387, ANDX1422, ANDX2043, ANDX3080, ANDX5329, ANDX5359, ANDY1217, ANDY4975, ANDZ1353, ANEN4892, ANEP2427, ANEQ2724, ANEQ4052, ANEQ4957, ANER1519, ANES2199, ANES4075, ANET0551, ANEX1706, ANEX3087, ANEX6024, ANEY1227, ANEY4329, ANEZ3406, ANFN1438, ANFN2851, ANFN3964, ANFP0871, ANFP2327 |
| VENEL16120 | Venovo 10F 16/120/1200mm OUS | 00801741102479 | ANDS0759, ANDS4832, ANDT2447, ANDV0263, ANDV0712, ANDV1232, ANDV2516, ANDW4409, ANDX1381, ANDX1415, ANDX2040, ANDX3073, ANDX5312, ANDY1223, ANDY4961, ANEN1063, ANEN4881, ANEP0865, ANEP2414, ANEQ1350, ANEQ2725, ANEQ4053, ANEQ4958, ANER1541, ANES2200, ANES4076, ANET0552, ANEW3420, ANEX0753, ANEX1711, ANEZ2091, ANEZ3407, ANFN3965, ANFP0872, ANFP2348 |
| VENEL16140 | Venovo 10F 16/140/1200mm OUS | 00801741102486 | ANDS1270, ANDS4833, ANDT2448, ANDU3083, ANDV1246, ANDX1379, ANDX2030, ANDX3069, ANDX5354, ANDY1214, ANEN3404, ANEP2436, ANEQ4054, ANES2201, ANEW3415, ANFN3966, ANFP0873, ANFP2350 |
| VENEL16160 | Venovo 10F 16/160/1200mm OUS | 00801741102493 | ANDS1284, ANDS2450, ANDS4786, ANDS4834, ANDT4133, ANDV0688, ANDV3574, ANDV4544, ANDW1488, ANDX0764, ANDX1370, ANDX1385, ANDX1421, ANDX5358, ANDY1228, ANEQ4055, |

| Catalogue Number (REF) | Product Name, Sheath Size, Stent Diameter x Length, Catheter Length | Unique Device Identifier (UDI-DI) | Lot Numbers |
|------------------------|---|-----------------------------------|--|
| | | | ANES2202, ANEX0677, ANEZ0916, ANEZ2092, ANEZ3408, ANFN3967, ANFP2372, ANFP3409 |
| VENEL18040 | Venovo 10F 18/40/1200mm OUS | 00801741102578 | ANDS1297, ANDS4835, ANDX1414, ANDX5356, ANDZ1340, ANEN1078, ANEN4872, ANEP5320, ANEQ2726, ANEQ4056, ANES2203, ANEU0742, ANEW3372, ANEX4718, ANEZ0917, ANFN3968, ANFP2351 |
| VENEL18060 | Venovo 10F 18/60/1200mm OUS | 00801741102585 | ANDS0755, ANDS4780, ANDT1230, ANDU3097, ANDV0264, ANDV0704, ANDV2512, ANDV4539, ANDW4342, ANDX1377, ANDX1409, ANDX5367, ANDY3297, ANDZ1337, ANEN2148, ANEN4893, ANEQ1351, ANEQ4057, ANEQ4959, ANES1036, ANES2204, ANET3791, ANEU3304, ANEW3419, ANEX3088, ANEX6158, ANEY2029, ANEZ3434, ANFP0874, ANFP2373 |
| VENEL18080 | Venovo 10F 18/80/1200mm OUS | 00801741102592 | ANDS1308, ANDS4836, ANDV0299, ANDV0701, ANDV3573, ANDV4542, ANDW4358, ANDX1384, ANDX1420, ANDX3078, ANDX5381, ANDY1236, ANDZ1347, ANDZ2293, ANEN2146, ANEN4873, ANEP2423, ANEQ4058, ANER1520, ANER5166, ANES2205, ANES4077, ANET0553, ANEV1713, ANEW3373, ANEW4227, ANEX0748, ANEX3097, ANEX6016, ANFP0875, ANFP2328 |
| VENEL18100 | Venovo 10F 18/100/1200mm OUS | 00801741102608 | ANDU1109, ANDV0692, ANDV3570, ANDW4375, ANDX1378, ANDX5304, ANDX5387, ANEN2151, ANEN3380, ANEN4888, ANEP3920, ANEQ4059, ANER4198, ANES1037, ANES4078, ANET3792, ANEW2045, ANEW3414, ANEX6021, ANFN1439, ANFP0876, ANFP2374 |
| VENEL18120 | Venovo 10F 18/120/1200mm OUS | 00801741102967 | ANDS2460, ANDS4837, ANDV1257, ANDW4392, ANDX5317, ANDY2467, ANDY3286, ANDZ1328, ANEP5318, ANEQ2727, ANEQ4060, ANES1038, ANES4079, ANET0554, ANEW3413, ANEX6020, ANEZ3435, ANFN3969, ANFP0910, ANFQ1011 |
| VENEL18140 | Venovo 10F 18/140/1200mm OUS | 00801741102974 | ANDS4779, ANDS4838, ANDV0686, ANDW1482, ANDW4410, ANDX1376, ANEP5319, ANEQ2728, ANES2206, ANES4080, ANFN3970, ANFP2352 |
| VENEL18160 | Venovo 10F 18/160/1200mm OUS | 00801741102981 | ANDS3978, ANDS4782, ANDV0705, ANDW1484, ANDW4344, ANDX1410, ANDX5377, ANER5150, ANES4081, ANEX0750, ANEX1710, ANEX3095, ANFN1440, ANFN3971, ANFP2375 |
| VENEL20040 | Venovo 10F 20/40/1200mm OUS | 00801741103063 | ANDS1028, ANDU3353, ANDX5313, ANDX6355, ANDZ1343, ANDZ2300, ANET1858, ANET1859, ANEW3374, ANEX6017, ANEZ3439, ANFP2353 |

| Catalogue Number (REF) | Product Name, Sheath Size, Stent Diameter x Length, Catheter Length | Unique Device Identifier (UDI-DI) | Lot Numbers |
|------------------------|---|-----------------------------------|--|
| VENEL20060 | Venovo 10F 20/60/1200mm OUS | 00801741103070 | ANDS1324, ANDT2896, ANDU1112, ANDV0699, ANDX1383, ANDX1419, ANDX5369, ANDY4967, ANDZ2295, ANEN3395, ANEP5327, ANEQ1352, ANEQ4061, ANER1521, ANER5119, ANES4082, ANEW3417, ANEX0755, ANEX3096, ANEZ3409, ANFP2321 |
| VENEL20080 | Venovo 10F 20/80/1200mm OUS | 00801741103087 | ANDS0758, ANDT4132, ANDU4060, ANDV0693, ANDV1210, ANDX1413, ANDX5355, ANDY3293, ANDZ2298, ANEN3406, ANEP0859, ANEP3922, ANEQ4062, ANER1522, ANER2793, ANER5135, ANES1039, ANES4083, ANET3793, ANEU3274, ANEX1703, ANEX4719, ANEY2030, ANEZ0918, ANEZ2093, ANEZ3426, ANFP2322 |
| VENEL20100 | Venovo 10F 20/100/1200mm OUS | 00801741103094 | ANDS1271, ANDV4531, ANDW4359, ANDX1411, ANDX5310, ANDY2459, ANDY3302, ANDZ2306, ANEN3382, ANEP3929, ANEP5333, ANEQ2729, ANER1523, ANER5151, ANES4084, ANEW3375, ANEZ0919, ANFN1441, ANFP2323, ANFP3398 |
| VENEL20120 | Venovo 10F 20/120/1200mm OUS | 00801741103100 | ANDS1285, ANDT1231, ANDV0689, ANDW4376, ANDX5357, ANDY3306, ANDZ2309, ANEP0851, ANEP5322, ANEQ4063, ANER0474, ANER1524, ANES1040, ANEZ2094, ANEZ3436, ANFP2324 |
| VENEL20140 | Venovo 10F 20/140/1200mm OUS | 00801741103117 | ANDS2469, ANDW4393, ANDX5378, ANES2207 |
| VENEL20160 | Venovo 10F 20/160/1200mm OUS | 00801741103124 | ANDS2481, ANDT1222, ANDU1110, ANDU1866, ANDX1369, ANDY3295, ANDZ1335, ANEN3386, ANEP0863, ANEP2418, ANEQ4064, ANEQ4960, ANES1041, ANES4085, ANEW3376, ANEW4228, ANEX0678, ANEX1698, ANEZ0920, ANFP0877, ANFP2376, ANFP3406 |

Appendix 2: Image of Representative Product Label

VENOVO™ Venous Stent System

Système de stent veineux • Venöses Stentsystem • Sistema di stent venoso • Sistema de stent venoso • Veneuze stentsysteem • Sistema de Stent Venoso • Σύστημα Φλεβικού Stent • Venøst stentsystem • Venøst stentsystem • Laskimostenttijärjestelmä • Venøst stentsystem • System stentow żylnych • Vénás sztent rendszer • Systém žilního stentu • Venöz Stent Sistemi • 靜脈血管支架系統 • 정맥 스텐트 시스템 • Система венозного стента • Venózný stentový systém • Venoosne stendisüsteem • Veninio stento sistema • Sistem cu stent venos • Венозна стент система • نظام الدعامات الوريدية

REF **VENEM10040**
 LOT **ANUGXXXX**

2999-01-01

.035"
(0.89 mm)

8F
(2.67 mm)

Manufacturer:
Angiomed GmbH & Co. Medizintechnik KG
 Wachhausstrasse 6
 76227 Karlsruhe
 Germany
 Tel: ++49 721 9445-0
 Fax: ++49 721 9445-111
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VENOVO™ Venous Stent System
 REF **VENEM10040** LOT **ANUGXXXX**
 2999-01-01
(01)0080174110193 9 (17)990101 (10)ANUGXXXX

CE
2797

STENT / Use by / Lot Number

(01)0080174110193 9 (17)990101 (10)ANUGXXXX

B05915 Rev. 0/02-15

LOT Number

Catalogue Number (REF)

Expiry Date

Unique Device Identifier (UDI-DI)