

20<sup>th</sup> 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**

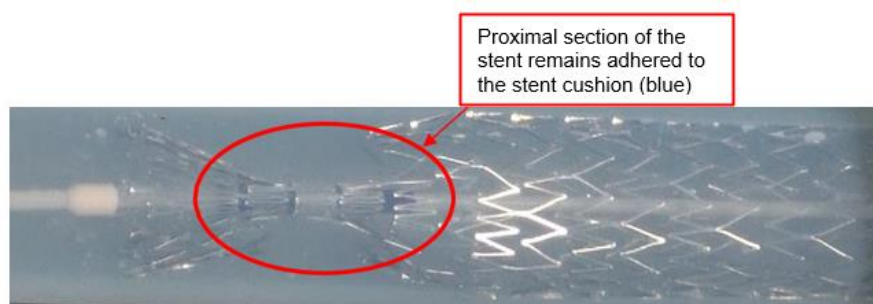
**This letter contains important information which requires your attention.**

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 30<sup>th</sup>, 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,

Lorna Darrock  
Senior Manager, Post-Market Quality EMEA



## 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 30<sup>th</sup>, 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)

<b>Name of Trust / Organisation</b>			
<b>Your Facility Address</b>			
<b>Postcode</b>			
<b>Telephone number</b>		<b>E-mail address</b>	
<b>Name of your supplier for this product</b> <i>(if not direct from BD)</i>			

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

<b>Your Name</b>		<b>Job Title</b>	
<b>Signature</b>		<b>Date</b>	

**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
<b>VENEM10040</b>	Venovo 8F 10/40/800mm OUS	00801741101939	ANDU2240, ANDY3304, ANDZ2288, ANDZ3827, ANEP2429, ANEP5328, ANES1042, ANES2208, ANEY3214, ANEY4323, ANFP2666
<b>VENEM10060</b>	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
<b>VENEM10080</b>	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
<b>VENEM10100</b>	Venovo 8F 10/100/800mm OUS	00801741101960	ANDY3305, ANEP0856, ANEP5323, ANEQ2731, ANEQ4067, ANER0516, ANES2210, ANEZ0922, ANFN1442, ANFN3973
<b>VENEM10120</b>	Venovo 8F 10/120/800mm OUS	00801741101977	ANDT1058, ANDU4075, ANDZ1348, ANEN1081, ANEP0857, ANEP3924, ANEQ4068, ANET3794, ANEX0680, ANEZ2096, ANFP2329
<b>VENEM10140</b>	Venovo 8F 10/140/800mm OUS	00801741101984	ANDZ2290, ANEP5324
<b>VENEM10160</b>	Venovo 8F 10/160/800mm OUS	00801741101991	ANDZ2296, ANEP5332, ANFP2330
<b>VENEM12040</b>	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
<b>VENEM12060</b>	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
<b>VENEM12080</b>	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
<b>VENEM12100</b>	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
<b>VENEM12120</b>	Venovo 8F 12/120/800mm OUS	00801741102110	ANDU4028, ANDV0275, ANDW4413, ANDX0751, ANDX5301, ANDY4972, ANEN1083, ANEN4883, ANEP5329, ANEQ2735, ANER5120, ANES4088, ANFP0880, ANFP2331
<b>VENEM12140</b>	Venovo 8F 12/140/800mm OUS	00801741102127	ANDU1103, ANDU4040, ANDX5327, ANDX5389, ANDZ1326, ANEP5309, ANEQ1356, ANEQ2736, ANER0519, ANER1535
<b>VENEM12160</b>	Venovo 8F 12/160/800mm OUS	00801741102134	ANDU1104, ANDY2452, ANDY3299, ANDZ3825, ANEN1084, ANEN4894, ANEQ4964, ANER0520
<b>VENEM14040</b>	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
<b>VENEM14060</b>	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
<b>VENEM14080</b>	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
<b>VENEM14100</b>	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
<b>VENEM14120</b>	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
<b>VENEM14140</b>	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
<b>VENEM14160</b>	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
<b>VENEM16040</b>	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
<b>VENEM16060</b>	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
<b>VENEM16080</b>	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
<b>VENEM16100</b>	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
<b>VENEM16120</b>	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
<b>VENEM16140</b>	Venovo 10F 16/140/800mm OUS	00801741102417	ANDS2462, ANDS4841, ANDX2786, ANDX5371, ANDZ3836, ANEN4891, ANEP3913, ANEP5312, ANEQ1374, ANER1547, ANFQ1013
<b>VENEM16160</b>	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
<b>VENEM18040</b>	Venovo 10F 18/40/800mm OUS	00801741102509	ANDT1056, ANDW4398, ANDX5360, ANDZ1349, ANDZ2302, ANEN4890, ANEP3917, ANEP5321, ANEQ4074, ANER1526, ANEW4261, ANEZ3421, ANFP3414
<b>VENEM18060</b>	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
<b>VENEM18080</b>	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
<b>VENEM18100</b>	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
<b>VENEM18120</b>	Venovo 10F 18/120/800mm OUS	00801741102547	ANDW2022, ANDW4350, ANDY3278, ANEN1069, ANEN3401, ANEP2419, ANFP2343
<b>VENEM18140</b>	Venovo 10F 18/140/800mm OUS	00801741102554	ANDW2025, ANDX0740, ANDY2466, ANDY3281, ANEN1085, ANEP0873, ANEP5314, ANEQ1371, ANEQ2751, ANEQ4974, ANER0527, ANER1512, ANES4097
<b>VENEM18160</b>	Venovo 10F 18/160/800mm OUS	00801741102561	ANDX0752, ANDX5380, ANDY3307, ANEN4889, ANEQ4075, ANFN1453
<b>VENEM20040</b>	Venovo 10F 20/40/800mm OUS	00801741102998	ANDV0697, ANDY2451, ANDY4970, ANDZ1344, ANEP3921, ANEQ4076, ANEQ4975, ANER0507, ANES4098, ANEZ0933, ANFP0914, ANFP4502
<b>VENEM20060</b>	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
<b>VENEM20080</b>	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
<b>VENEM20100</b>	Venovo 10F 20/100/800mm OUS	00801741103025	ANDW1490, ANDW2027, ANDY2455, ANDY3285, ANEP0874, ANEP5310, ANER1527, ANES4101, ANET2532, ANEU0743
<b>VENEM20120</b>	Venovo 10F 20/120/800mm OUS	00801741103032	ANDW2024, ANDZ2294, ANEP0876, ANEP5331, ANES2221
<b>VENEM20140</b>	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
<b>VENEM20160</b>	Venovo 10F 20/160/800mm OUS	00801741103056	ANDV0253, ANDW2005, ANEP0875, ANEP5315, ANEQ2754, ANES2222, ANFN3988
<b>VENEL10040</b>	Venovo 8F 10/40/1200mm OUS	00801741102004	ANDU2239, ANDW4406, ANDX5374, ANEP3938, ANEQ2716, ANES2187
<b>VENEL10060</b>	Venovo 8F 10/60/1200mm OUS	00801741104664	ANDT1057, ANDU4074, ANDW4338, ANDX5309, ANDZ2308, ANEP0852, ANEP3936, ANEQ4036, ANEQ4945, ANER5149, ANET3785, ANEX0671, ANEX3092, ANEZ0906, ANEZ3430, ANFN1430, ANFP2368
<b>VENEL10080</b>	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
<b>VENEL10100</b>	Venovo 8F 10/100/1200mm OUS	00801741102035	ANDT0505, ANDT1054, ANDY2469, ANDY4963, ANDZ1345, ANEP0862, ANEP2417, ANEW2047, ANEW4217, ANEY3209, ANEY4322, ANFN1431, ANFN3945, ANFP2370
<b>VENEL10120</b>	Venovo 8F 10/120/1200mm OUS	00801741102042	ANEQ1347, ANES2188, ANFP2349
<b>VENEL10140</b>	Venovo 8F 10/140/1200mm OUS	00801741102059	ANDU1108, ANDY3280, ANEN3385, ANEQ1348, ANEQ4038
<b>VENEL10160</b>	Venovo 8F10/160/1200mm OUS	00801741102066	ANDS1027, ANDW1996, ANDX6354, ANDY2448, ANET1855
<b>VENEL12040</b>	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
<b>VENEL12060</b>	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
<b>VENEL12080</b>	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
<b>VENEL12100</b>	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
<b>VENEL12120</b>	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
<b>VENEL12140</b>	Venovo 8F 12/140/1200mm OUS	00801741102202	ANDS1282, ANDU2245, ANDW2002, ANDW4389, ANDX5376, ANDY3288, ANEN1072, ANEN3387, ANEP2430, ANEQ4043, ANER1517, ANES4064, ANFN3952, ANFN3953, ANFP0860
<b>VENEL12160</b>	Venovo 8F 12/160/1200mm OUS	00801741102219	ANDS4776, ANDT1686, ANDV4536, ANDX1403, ANDX5375, ANDY3287, ANEP2412, ANEQ4948, ANES4065, ANEZ3427, ANFN3954, ANFP0861
<b>VENEL14040</b>	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
<b>VENEL14060</b>	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
<b>VENEL14080</b>	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
<b>VENEL14100</b>	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
<b>VENEL14120</b>	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
<b>VENEL14140</b>	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
<b>VENEL14160</b>	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
<b>VENEL16040</b>	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
<b>VENEL16060</b>	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
<b>VENEL16080</b>	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
<b>VENEL16100</b>	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
<b>VENEL16120</b>	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
<b>VENEL16140</b>	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
<b>VENEL16160</b>	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
<b>VENEL18040</b>	Venovo 10F 18/40/1200mm OUS	00801741102578	ANDS1297, ANDS4835, ANDX1414, ANDX5356, ANDZ1340, ANEN1078, ANEN4872, ANEP5320, ANEQ2726, ANEQ4056, ANES2203, ANEU0742, ANEW3372, ANEX4718, ANEZ0917, ANFN3968, ANFP2351
<b>VENEL18060</b>	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
<b>VENEL18080</b>	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
<b>VENEL18100</b>	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
<b>VENEL18120</b>	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
<b>VENEL18140</b>	Venovo 10F 18/140/1200mm OUS	00801741102974	ANDS4779, ANDS4838, ANDV0686, ANDW1482, ANDW4410, ANDX1376, ANEP5319, ANEQ2728, ANES2206, ANES4080, ANFN3970, ANFP2352
<b>VENEL18160</b>	Venovo 10F 18/160/1200mm OUS	00801741102981	ANDS3978, ANDS4782, ANDV0705, ANDW1484, ANDW4344, ANDX1410, ANDX5377, ANER5150, ANES4081, ANEX0750, ANEX1710, ANEX3095, ANFN1440, ANFN3971, ANFP2375
<b>VENEL20040</b>	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
<b>VENEL20060</b>	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
<b>VENEL20080</b>	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
<b>VENEL20100</b>	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
<b>VENEL20120</b>	Venovo 10F 20/120/1200mm OUS	00801741103100	ANDS1285, ANDT1231, ANDV0689, ANDW4376, ANDX5357, ANDY3306, ANDZ2309, ANEP0851, ANEP5322, ANEQ4063, ANER0474, ANER1524, ANES1040, ANEZ2094, ANEZ3436, ANFP2324
<b>VENEL20140</b>	Venovo 10F 20/140/1200mm OUS	00801741103117	ANDS2469, ANDW4393, ANDX5378, ANES2207
<b>VENEL20160</b>	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 • Venosne stendisüsteem • Veninio stento sistema • Sistem cu stent venos • Венозна стент система • نظام الدعامات الوريدية

**40 mm** (width)  
**10 mm** (height)

**111.5 cm** (total length)  
**80 cm** (catheter length)

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

**2999-01-01**

**.035"**  
(0.89 mm)

**8F**  
(2.67 mm)

**VENOVO™ Venous Stent System**

**REF VENEM10040** **LOT ANUGXXXX**  
(01)0080174110193 9 (17)990101 (10)ANUGXXXX

**2999-01-01**

**VENOVO™ Venous Stent System**

**REF VENEM10040** **LOT ANUGXXXX**  
(01)0080174110193 9 (17)990101 (10)ANUGXXXX

**2999-01-01**

**VENOVO™ Venous Stent System**

**REF VENEM10040** **LOT ANUGXXXX**  
(01)0080174110193 9 (17)990101 (10)ANUGXXXX

**2999-01-01**

**STERILE EO**

**CE 2797**

Manufacturer: **Angiomed GmbH & Co. Medizintechnik KG**  
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**STERILE EO**

**STENT / Use by / Lot Number**

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

LOT Number

Catalogue Number (REF)

Expiry Date

Unique Device Identifier (UDI-DI)