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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.

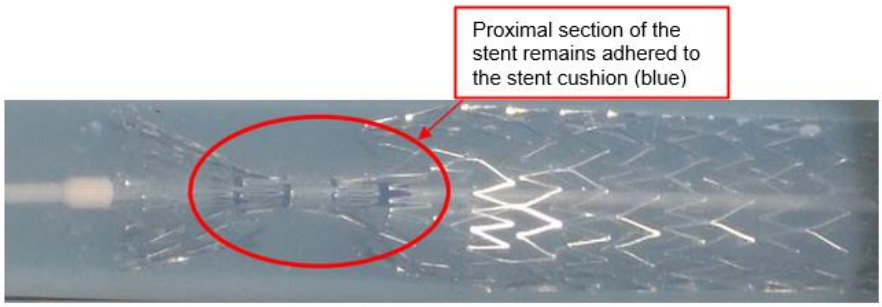

Figure 1: Proximal end of the stent remains connected to the stent cushion material.

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

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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,

……
Senior Manager, Post-Market Quality EMEA

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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)

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

	Facility / Hospital Name	**Postcode**
Please list all Facilities / Hospitals covered by your response *(e.g. other hospitals within your Trust)*		

Your Name		**Job Title**	
Signature		**Date**	

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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,

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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,

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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,

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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

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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

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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,

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			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,

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			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

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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,

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			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

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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

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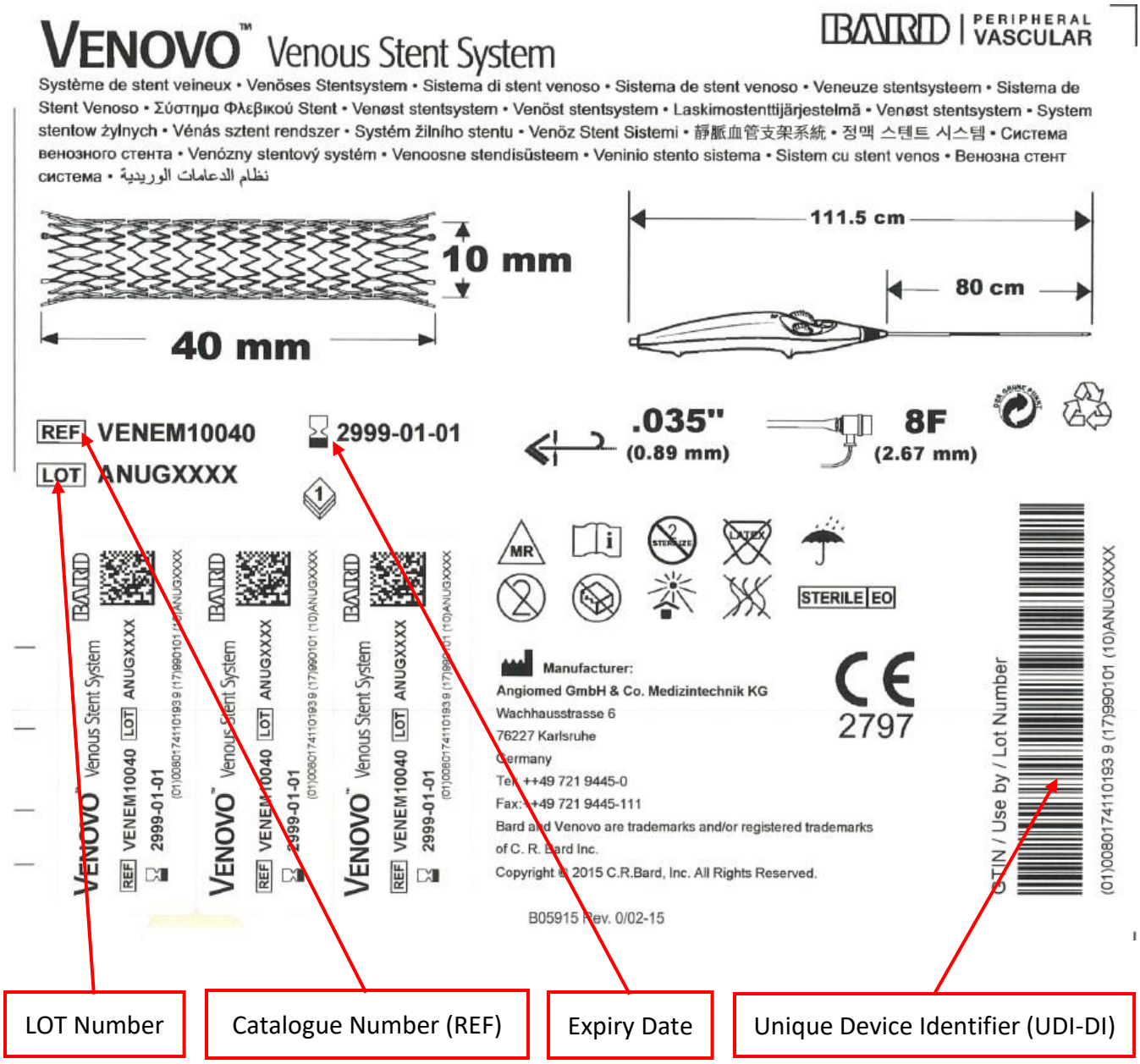
Appendix 2: Image of Representative Product Label