

XX maj 2021

## **NUJNO: VARNOSTNO OBVESTILO — PI-21-4000**

### **Sistem venske opornice Venovo™**

**REF.:** Glejte Dodatek 1

**LOTI:** Vsi izdelki, ki jim ni potekel rok uporabnosti

**Vrsta ukrepa:** Umik izdelka

**Prejemniki: specialisti za vene, klinično osebje, odgovorne osebe za obvladovanje tveganj, biomedicinsko osebje**

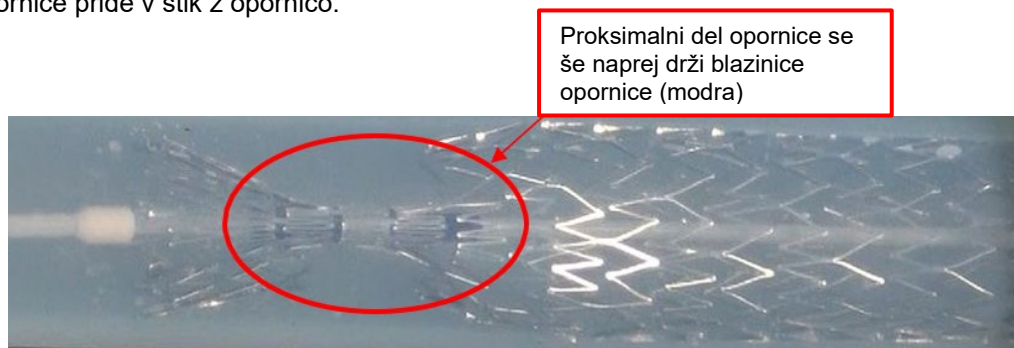
**Ta dopis vsebuje pomembne informacije, ki zahtevajo vašo pozornost.**

Spoštovana stranka,

Družba BD pošilja to varnostno obvestilo zaradi umika vseh nepretečenih lotov **sistema venske opornice Venovo™** (glejte Dodatek 1 za kataloške številke/reference in številke lotov, ki jih družba BD dobavlja na trg EMEA). Naši distribucijski sezname kažejo, da je vaša organizacija morda prejela prizadete pripomočke.

#### **Opis težave**

Družba BD je na podlagi povratnih informacij strank ugotovila, da se lahko pri **sistemu venske opornice Venovo™** pojavijo težave z namestitvijo, ker proksimalnega konca žilne opornice ni mogoče razširiti takoj po uvedbi. Proksimalni konec opornice se namesto tega še naprej drži blazinice opornice na uvajalnem sistemu, kot je prikazano na sliki 1 spodaj. Dodatne raziskovalne študije predmetnih testnih vzorcev so pokazale sledi materiala blazinice (biokompatibilni silikon medicinske kakovosti), ki se trdno držijo površine opornice samo na delu, kjer blazinica opornice pride v stik z opornico.



**Slika 1:** Proksimalni del opornice se še naprej drži materiala blazinice opornice.

#### **Klinični vpliv**

V primerih, ko se opornica sama razširi, ni večjih tveganj za škodo. V nasprotnem primeru bi lahko prekomerna manipulacija ali uporaba sile na uvajalnem sistemu za kateter pri poskusu razširitve opornice povzročila večjo ali manjšo posledično škodo. Potencialna škoda vključuje daljše trajanje posega, poškodbo ali deformacijo opornice, poškodbo žile in/ali hemodinamične motnje, ki lahko vplivajo na pretok krvi in/ali trombotični dogodek.

Družba BD je do danes prejela pritožbe za različne velikosti izdelkov iz ponudbe. Nevarnost se pojavi, ko se opornica v osrednjem območju blizu proksimalnega konca ne razširi takoj ob namestitvi in zdravnik morda ne bo pustil dovolj časa za normalno širitev, temveč bo poskušal manipulirati z opornico ali uporabiti druge intravaskularne pripomočke ali tehnike za razširitev opornice. To lahko privede do nepravilne postavitve ali poškodbe opornice in žile. Prenos biokompatibilnega silikona medicinske kakovosti, ki se drži notranje površine

opornice, bi lahko povzročil vnetni odziv ali zamašitev/obstrukcijo vaskulature, če je silikona precej in se je ločil od površine.

Če je bil pripomoček že varno uporabljen, spremljanje bolnikov ni potrebno. Prosimo, sporočite vse neželene posledice za zdravje, ki so se pojavile pri uporabi tega izdelka družbe BD, če tega še niste storili.

### **Korektivni ukrepi družbe BD**

Družba BD je prenehala proizvajati izdelek, ki je predmet tega varnostnega obvestila, in izvaja podrobno preiskavo o osnovnem vzroku težave.

### **Nasveti glede ukrepov, ki jih mora sprejeti uporabnik**

1. Prosimo, prenehajte uporabljati sistem venske opornice **Venovo™**.
2. Poiščite, izločite in uničite vse lotesistema venske opornice **Venovo™** (glejte Dodatek 1 za kataloške številke (REF) in številke lotov).
  - a. Vsi loti z rokom uporabnosti po aprilu 2021 so predmet umika izdelka (glejte Dodatek 2, da ugotovite datum poteka roka uporabnosti na oznaki izdelka).
3. To varnostno obvestilo razpošljite vsem osebam v vaši ustanovi, ki morda uporabljajo **sistem venske opornice Venovo™**.
4. Če ste izdelek distribuirali naprej, zadevne uporabnike identificirajte in jih takoj obvestite o tem varnostnem obvestilu.
5. Izpolnjen obrazec za potrditev stranke (odgovor) na strani **3** <<email address>> **vrnite čim prej oziroma najpozneje do date**.
  - a. OPOMBA: Če izdelka ne uporabljate več, je še vedno pomembno, da obrazec za odziv stranke posredujete za namene usklajevanja.
  - b. OPOMBA: Družba BD bo po prejemu izpolnjenega obrazca za odgovor stranke izdala dobropis vsem strankam, ki jih je prizadel odpoklic.

Če imate kakršna koli vprašanja ali težave, povezane z izdelkom, ali če naletite na težavo, opisano v tem varnostnem obvestilu, se obrnite na lokalnega predstavnika družbe BD.

Potrjujemo, da smo o teh ukrepih obvestili ustrezne regulativne agencije.

Družba BD je zavezana temu, da strankam zagotavlja varne in učinkovite izdelke, to varnostno obvestilo pa je bilo izdano ob upoštevanju te zaveze.

Zahvaljujemo se vam za pozornost in sodelovanje.

S spoštovanjem,

## Obrazec za potrditev – PI-21-4000

### Sistem venske opornice Venovo™

Ta obrazec preberite skupaj z varnostnim obvestilom PI-21-4000 ter ga vrnite izpolnjenega in podpisanega čim prej oz. **najkasneje do date** na <insert fax/email address here>.

**S spodnjim podpisom potrjujete, da ste to obvestilo prebrali, razumeli in izvedli vse priporočene ukrepe skladno z zahtevami.**

Spodaj označite ustrezno polje.

V lasti nimamo nobenega zadevnega izdelka.

#### ALI

Imamo enote prizadetega izdelka in potrjujemo, da je bilo uničeno naslednje število spodaj navedenih izdelkov (**prosimo, priložite dodatne sezname, kot je potrebno**).

Kataloška številka (REF)	Številka lota	Količina uničenih enot		Kataloška številka (REF)	Številka lota	Količina uničenih enot (enote)

<b>Ime trusta/organizacije</b>			
<b>Naslov vaše ustanove</b>			
<b>Poštna številka</b>			
<b>Telefonska številka</b>		<b>E-poštni naslov</b>	
<b>Ime vašega dobavitelja tega izdelka</b> (če ni pridobljen neposredno pri družbi BD)			

<b>Prosimo, navedite vse ustanove/bolnišnice, vključene v vaš odziv</b>  (npr. druge bolnišnice v okviru vašega trusta)	<b>Ime ustanove/bolnišnice</b>	<b>Poštna številka</b>

<b>Vaše ime</b>		<b>Službeni naziv</b>	
<b>Podpis</b>		<b>Datum</b>	

**Dodatek 1: Prizadeti sistem opornice Venovo™ – kataloška številka (REF) in številke lotov za območje EMEA**

Kataloška številka (REF)	Ime izdelka, velikost tulca, premer opornice x dolžina, dolžina katetra	Edinstveni identifikator pripomočka (UDI-DI)	Številke lotov
<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,

Kataloška številka (REF)	Ime izdelka, velikost tulca, premer opornice x dolžina, dolžina katetra	Edinstveni identifikator pripomočka (UDI-DI)	Številke lotov
			ANDX0727, ANDX2032, ANDX2426, ANDX3063, ANDX5307, ANDY1221, ANDY2464, ANDY3291, 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,

Kataloška številka (REF)	Ime izdelka, velikost tulca, premer opornice x dolžina, dolžina katetra	Edinstveni identifikator pripomočka (UDI-DI)	Številke lotov
			ANDY2449, ANDY3282, ANDZ1325, ANDZ2282, ANDZ3821, ANEN1062, ANEN3390, ANEN4871, ANEP2434, ANEQ0215, ANEQ1359, ANEQ4967, 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,

Kataloška številka (REF)	Ime izdelka, velikost tulca, premer opornice x dolžina, dolžina katetra	Edinstveni identifikator pripomočka (UDI-DI)	Številke lotov
			ANEP3928, ANEQ1364, ANEQ2744, ANER1539, ANES1046, ANES2217, ANES4092, ANEW3411, ANEX0751, ANEZ0930, ANEZ2105, ANEZ3418, 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,

Kataloška številka (REF)	Ime izdelka, velikost tulca, premer opornice x dolžina, dolžina katetra	Edinstveni identifikator pripomočka (UDI-DI)	Številke lotov
			ANEN4875, ANEP2411, ANEQ1368, ANEQ2748, ANEQ4972, ANER1546, ANES1033, ANEZ0984, ANFN1451, ANFN3986, ANFP0888, ANFP0889, ANFP2335, ANFP3413
<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



Kataloška številka (REF)	Ime izdelka, velikost tulca, premer opornice x dolžina, dolžina katetra	Edinstveni identifikator pripomočka (UDI-DI)	Številke lotov
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
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,

Kataloška številka (REF)	Ime izdelka, velikost tulca, premer opornice x dolžina, dolžina katetra	Edinstveni identifikator pripomočka (UDI-DI)	Številke lotov
			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, 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,

Kataloška številka (REF)	Ime izdelka, velikost tulca, premer opornice x dolžina, dolžina katetra	Edinstveni identifikator pripomočka (UDI-DI)	Številke lotov
			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, 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,

Kataloška številka (REF)	Ime izdelka, velikost tulca, premer opornice x dolžina, dolžina katetra	Edinstveni identifikator pripomočka (UDI-DI)	Številke lotov
			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
<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

Kataloška številka (REF)	Ime izdelka, velikost tulca, premer opornice x dolžina, dolžina katetra	Edinstveni identifikator pripomočka (UDI-DI)	Številke lotov
<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, 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

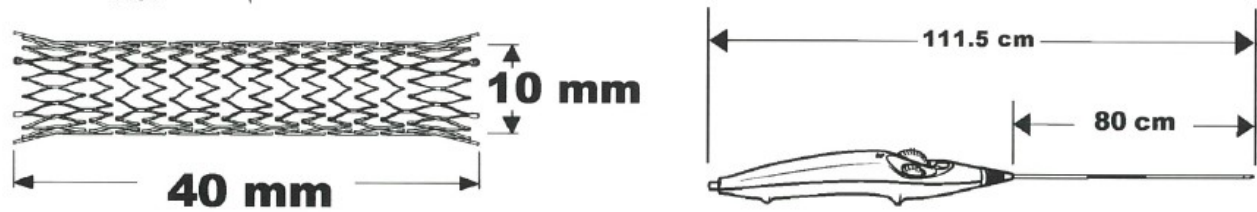
Kataloška številka (REF)	Ime izdelka, velikost tulca, premer opornice x dolžina, dolžina katetra	Edinstveni identifikator pripomočka (UDI-DI)	Številke lotov
VENEL18140	Venovo 10F 18/140/1200mm OUS	00801741102974	ANDS4779, ANDS4838, ANDV0686, ANDW1482, ANDW4410, ANDX1376, ANEP5319, ANEQ2728, ANES2206, 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
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

**Dodatek 2:** Slika reprezentativne oznake izdelka

# VENOVO™ Venous Stent System

**BARD** | PERIPHERAL VASCULAR

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 • Венозная стент система • نظام الدعامات الوريدية



REF **VENEM10040**      2999-01-01  
 LOT **ANUGXXXX**

**.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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**CE**  
 2797



Številka LOT

Kataloška številka (REF)

Rok uporabnosti

Edinstveni identifikator pripomočka (UDI-DI)