

URGENT MEDICAL DEVICE RECALL NOTICE

Name of Affected Products: 16F Dual-Valved Splittable Sheath Introducer

Action Required: Destroy at the point of use

Merit Medical Systems, Inc. (Merit) is conducting a voluntary recall of the Merit 16F Dual-Valved Splittable Sheath Introducer due to a design defect. Specifically, the sheath introducer may not split as intended. This sheath introducer is used in several Merit finished devices, a complete list of affected products and lots can be found in the table attached or can be accessed at "<https://www.merit.com/products/documents/product-notices/16FDualValvedSheath-recall/>".

Merit has received customer complaints regarding this issue, some of which involve patient injury. Failure of the sheath introducer to split as intended may result in hemorrhage, foreign bodies, and procedure delay.

Merit is requesting you to immediately discontinue the use of the 16F Dual-Valved Splittable Sheath Introducer and destroy the sheath introducer at point of use. The other products included with the sheath introducer may continue to be used.

Actions required of you:

1. Please immediately determine if any of the devices identified in the attached Customer Response Form (CRF) are within your facility.
2. A picture of the 16F Dual-Valved Splittable Sheath Introducer is attached to help you identify the product. Please place this notice and the picture on or near the affected Merit product in your inventory (if applicable).



3. Please immediately discontinue the use of the 16F Dual-Valved Splittable Sheath Introducer and destroy the sheath introducer at the point of use. Only the 16F Dual-Valved Splittable Sheath Introducer component should be discarded at the point of use; the rest of the finished good components remain safe for clinical use.
 - a. Note: The introducer is sealed within the sterile barrier and cannot be removed or destroyed at the inventory level. Opening the unit packaging would compromise the sterility of the remaining components, and therefore should occur at the point of use.
4. Ensure that applicable personnel within your organization are made aware of this field action.
5. If the product has been further distributed to other facilities, institutions, or manufacturers, please ensure this notice is immediately shared with them and note the quantity distributed on the CRF. Additional distribution details may be required by health authorities.

6. Please fill out, scan and email the completed Customer Response Form to Customer Service at RESPONSE@merit.com within 10 business days. All affected product shipped to you must be accounted for on the CRF.
7. If requesting alternative standalone single valve sheaths to support kits, please use Product code: DCVP1600, and contact RESPONSE@merit.com, along with the completed Customer Response Form.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

If you have any questions concerning this communication, please don't hesitate to contact your Merit Sales Representative or Merit Customer Service via email at RESPONSE@merit.com or via phone at +1 800 356 3748 | Hours: 6 am to 6 pm MST | Mon-Fri.

Merit Medical is committed to providing high quality products to you and apologizes for any inconvenience this field action may cause.

Enclosure(s)

Affected Lots Table

(16F Dual-Valved Splittable Sheath Introducer)

Catalog Code	Lot Number
CENFP15K/A	H3357122
CENFP15K/B	H2797565
CENFP17K/A	H2643728
	H2644554
	H2755843
	H2777866
	H3357123
CENFP19K/A	H2415318
	H2466455
	H2466456
	H2608337
	H2632772
	H2632921
	H2643525
	H2643729
	H2658246
	H2658395
	H2663614
	H2708827
	H2777850
	H2817064
	H2817066
	H2834183
	H2834184
	H2835774
	H2875195
	H2892153
	H2900496
	H2900649
	H2918430
	H2938756
	H2982068
	H2998532
	H3019164
	H3028009
	H3089474
	H3096774
	H3101839
	H3110067
	H3123035
	H3131873
	H3139507
	H3143969
	H3152236
	H3328470
	H3332131
	H3332133
	H3357124
	H3383280
H3398546	
CENFP23K/A	H2368055
	H2460265
	H2543292
	H2612929

Catalog Code	Lot Number
DC21453227/C	H2630602
DC21454035/C	H2628887
DC21455550/C	H2630553
	H2659229
FCL-174-00/B	I2362705
	I2370091
	I2370711
	I2370712
	I2377840
	I2377841
	I2391548
	I2397290
	I2415120
	I2417400
	I2417401
	I2417402
	I2428656
	I2428657
	I2428658
	I2428659
	I2469204
	I2469205
	I2469206
	I2469207
	I2473119
	I2485668
	I2485669
	I2485670
	I2485671
	I2485672
	I2485673
	I2485674
	I2485675
	I2496785
	I2496787
	I2496790
	I2516610
	I2516611
	I2516612
	I2516613
	I2516614
	I2516615
	I2539710
	I2539711
	I2539713
	I2539714
I2539715	
I2539717	
I2561078	
I2561079	
I2561081	
I2561082	
I2573969	
I2606642	

Catalog Code	Lot Number
H965103028031/A	I3120008
	I3156395
	I3161825
	I3178917
	I3202927
	I3236144
	I3236147
	I3236157
	I3236162
	I3236164
I3368281	
H965103028031/EU	I3219447
	I3270828
H965103028041/A	I3288591
	I2838431
	I2910263
	I2910264
	I2910265
	I2973186
	I2975804
	I2975805
	I2979959
	I2979960
	I3015758
	I3064923
	I3064925
	I3072563
	I3108163
	I3120003
	I3120006
	I3156399
	I3165147
	I3175748
	I3178899
	I3208677
	I3236145
	I3236148
	I3236158
	I3236163
I3236165	
I3312321	
I3315961	
I3323271	
I3347039	
H965103028041/EU	I3217180
	I3270829
H965103028051/A	I3302439
	I2929337
H965103028051/EU	I2997999
	I3311219
H965103028061/A	I3219448
	I3270832
	I3302440
	I2920321

Affected Lots Table

(16F Dual-Valved Splittable Sheath Introducer)

Catalog Code	Lot Number
CENFP23K/A	H2622368
	H2623456
	H2631340
	H2640771
	H2663612
	H2663613
	H2719753
	H2812164
	H2817069
	H2834179
	H2834181
	H2847016
	H2868174
	H2880283
	H2897527
	H2900497
	H2900550
	H2907334
	H2911460
	H2938761
	H2978595
	H2990699
	H3004608
	H3019163
	H3049760
	H3049761
	H3052479
	H3071291
	H3075039
	H3089475
	H3092914
	H3096777
	H3104588
	H3107507
	H3120779
	H3131874
	H3143970
	H3145117
	H3191613
	H3211721
H3316467	
H3328494	
H3332218	
H3332219	
H3332220	
H3351695	
CENFP27K/A	H2286892
	H2480924
	H2623453
	H2643731
	H2643732
	H2653626
	H2663616
	H2777861

Catalog Code	Lot Number
FCL-174-00/B	I2606643
	I2606644
	I2606645
	I2619459
	I2621646
	I2621647
	I2621648
	I2621649
	I2621650
	I2621651
	I2621652
	I2621653
	I2642738
	I2642739
	I2642740
	I2644031
	I2644032
	I2644033
	I2644034
	I2644036
	I2661872
	I2661873
	I2661874
	I2661875
	I2661876
	I2661877
	I2708121
	I2708122
	I2708123
	I2708124
	I2720071
	I2720074
	I2720075
	I2720076
	I2720077
	I2720078
	I2720079
	I2729938
	I2729939
	I2729940
I2729941	
I2729942	
I2729943	
I2729944	
I2729945	
I2759253	
I2759254	
I2759255	
I2759256	
I2759257	
I2759258	
I2759260	
I2759261	
I2759268	

Catalog Code	Lot Number
H965103028061/A	I2980492
	I3154945
H965103028061/EU	I3254911
	I3196140
H965103028070/A	I3270833
	I3312332
	I3015819
H965103028070/EU	I3113237
	I3170179
	I3247943
H965103028080/A	I3288616
	I3255305
H965103028080/EU	I3307483
	I3002021
	I3064921
H965103028090/A	I3178919
	I3302450
	I3343031
H965103028090/EU	I3196137
	I3302445
H965103028090/A	I3334625
	I2920165
	I3103138
H965103028090/EU	I3178922
	I3290565
	I3196135
H965103028161/A	I3302441
	I3352493
H965103028181/A	I2914680
	I2980457
	I3098578
	I2890978
	I2902665
	I2909617
	I2909618
	I2929338
	I3076856
	I3085067
	I3098579
	I3178915
	I3254917
	I3255301
I3283028	
H965103028191/A	H2936911
	I2870746
	I2908636
	I2909637
	I2910257
	I2920337
	I2927199
	I3144031
I3164176	
I3219662	
I3236146	

Affected Lots Table

(16F Dual-Valved Splittable Sheath Introducer)

Catalog Code	Lot Number
	H2798003
CENFP27K/A	H2833668
	H2834185
	H2880284
	H2900619
	H2907339
	H2910719
	H2911565
	H2978601
	H2986646
	H2998508
	H3004606
	H3013812
	H3019148
	H3096779
	H3110068
	H3131879
	H3143988
	H3145119
	H3156431
	H3357125
H3383281	
CENFP31K/A	H2623455
	H2643737
	H2663617
	H3052480
	H3071293
	H3071294
	H3110069
	H3113265
	H3143998
	H3196708
	H3328496
	H3332421
	CENFT15K
H2907340	
H2911505	
H2978606	
H3004602	
CENFT15K/D	H3071303
	H3075046
	H3116838
CENFT17K	H2750962
	H2755782
	H2777600
	H3034899
	H3059017
	H3059018
H3062346	
CENFT17K/A	H2911456
CENFT17K/D	H3139508
CENFT19K	H2632775
	H2658397
	H2709212

Catalog Code	Lot Number
	I2759269
FCL-174-00/B	I2781492
	I2781493
	I2781494
	I2781495
	I2781496
	I2781497
	I2781498
	I2781499
	I2788883
	I2788884
	I2788885
	I2788886
	I2788887
	I2788888
	I2788889
	I2788890
	I2788891
	I2788892
	I2810292
	I2810293
	I2810294
	I2810296
	I2810297
	I2841474
	I2841475
	I2849305
	I2849306
	I2854355
	I2854356
	I2854357
	I2860217
	I2860218
	I2861568
	I2861569
	I2871785
	I2871786
	I2871787
I2883689	
I2883691	
I2890983	
I2904247	
I2904250	
I2927630	
I2927631	
I2942563	
I2942564	
I2942565	
I2942566	
I2942567	
I2942568	
I2942569	
I2942570	
I2942571	

Catalog Code	Lot Number
	I3288655
H965103028191/A	I3368110
H965103028191/EU	I3309111
H965103028201/A	I2973187
	I3173621
	I3178898
	I3236149
	I3288573
H965103028211/A	I2909764
	I3144033
	I3302435
	I3343037
H965103028220/A	I2909788
	I3394016
H965103028230/A	I2982337
	I3044847
	I3191920
	I3288574
	I3334623
H965103028240/A	I2929339
	I3002035
	I3049565
	I3108165
	I3254923
	I3302451
H965103038181/A	I2890952
	I2902661
	I2902662
K12-03886DP	H3138928
H787103028235/A	I3178905
H965103028011/A	I3105589
	I3115469
	I3314948
	I3343030
H965103028021/A	I2985084
	I3235297
	I3302100
	I3343023
H965103028021/EU	I3254932
H965103028031/A	I2890967
	I2909607
	I2909610
	I2909613
	I2922255
	I2928443
	I2928445
	I2973185
	I2975817
	I2979931
	I2979932
	I3010126
	I3015730
I3015731	
I3072562	

Affected Lots Table

(16F Dual-Valved Splittable Sheath Introducer)

Catalog Code	Lot Number	
CENFT19K	H2817067	
	H2821275	
	H2835372	
	H2856854	
	H2864393S1	
	H2884659	
	H2900500	
	H2907322	
	H2907349	
	H2918517	
	H2933863	
	H2937909	
	H2937910	
	H2978622	
	H2999167	
	H3019145	
	H3034898	
H3049764		
CENFT19K/A	H2907422	
CENFT19K/B	H2801414	
CENFT19K/D	H3049766	
	H3049767	
	H3071304	
	H3075050	
	H3089478	
	H3126999	
	H3144001	
	H3152238	
	H3156433	
	H3162590	
	H3179819	
	H3196714	
	H3221338	
	H3233980	
	H3239914	
	H3253651	
	H3261220	
	H3283451	
	H3306069	
	H3350849	
	H3357127	
	H3357128	
	H3365884	
	H3372112	
	H3398547	
	CENFT23K	H2368107
		H2657097
H2709213		
H2719652		
H2783586		
H2812165		
H2834187		
H2834188		
H2864382S1		

Catalog Code	Lot Number
FCL-174-00/B	I2942667
	I2942669
	I2988895
	I2988896
	I2988897
	I3013245
	I3013246
	I3075993
	I3075994
	I3075995
	I3075996
	I3075997
	I3083308
	I3083309
	I3083310
	I3083312
	I3083314
	I3083317
	I3098214
	I3098256
	I3127468
	I3138237
	I3138238
	I3138239
	I3138240
	I3138241
	I3138242
	I3159773
	I3159774
	I3159776
I3159777	
I3186218	
I3257331	
H787103028015/A	I3049562
H787103028025/A	I3309371
H787103028031/A	I2929299
	I3072553
	I3154760
	I3175731
I3178921	
I3315957	
H787103028035/A	I2910259
	I2910261
	I2910262
	I2980545
	I2995795
	I3021388
	I3076851
	I3085062
	I3219446
	I3219454
I3255314	
I3288649	
I3334618	

Catalog Code	Lot Number
	I3108161
	I3115487

Affected Lots Table

(16F Dual-Valved Splittable Sheath Introducer)

Catalog Code	Lot Number
	H2870049
	H2892155
	H2898665
CENFT23K	H2900501
	H2907365
	H2911451
	H2911452
	H2934395
	H2971862
	H2986161
	H2986162
	H2998549
	H3007025
	H3019139
	H3028000
	CENFT23K/A
H2817068	
H2911454	
H2990794	
H3013830	
H3019136	
CENFT23K/B	H3034895
	H2801413
CENFT23K/D	H3049771
	H3049772
	H3071305
	H3071306
	H3145122
	H3152240
	H3170518
	H3196713
	H3201956
	H3211729
	H3221345
	H3233987
	H3239915
	H3249275
	H3275167
	H3301761
	H3306072
	H3323733
	H3332225
	H3342600
CENFT27K	H2618709
	H2642807
	H2783590
	H2817065
	H2835374
	H2884649
	H2892156
	H2900227
	H2910433
	H2937927
	H2949972

Catalog Code	Lot Number
H787103028041/A	I2909647
	I3115465
	I3178909
	I3236154
H787103028045/A	I3004072
	I3015761
	I3044845
	I3072554
	I3108153
	I3176646
	I3178918
	I3213147
	I3219456
	I3281054
	I3334627
H787103028051/A	I2995730
	I3072556
	I3213145
	I3219455
	I3288560
H787103028055/A	I3302443
	I3178903
H787103028061/A	I2929300
	I2995814
	I3072557
	I3165105
	I3207168
H787103028075/A	I3236155
	I3334619
	I2995817
H787103028085/A	I3209313
	I3270826
H787103028085/A	I2890956
	I3072561
	I3108155
	I3288562
H787103028095/A	I3302444
	I2909667
	I2929315
	I3021151
	I3098576
H787103028165/A	I3219463
	I3288581
	I3049563
H787103028181/A	I2929317
	I3178900
H787103028185/A	I3208675
	I2927170
	I2929318
	I2929319
	I3002050
	I3015762
	I3021450
	I3049572

Catalog Code	Lot Number
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Affected Lots Table

(16F Dual-Valved Splittable Sheath Introducer)

Catalog Code	Lot Number
	H2971939
	H3019133
	H3027993
	H3059051
CENFT27K	H3062349
	H3071308
CENFT27K/A	H2831335
	H2847031
	H2911463
	H3019129
CENFT27K/B	H2801412
CENFT27K/D	H3049776
	H3049777
	H3080509
	H3152241
	H3179811
	H3186110
	H3191615
	H3201954
	H3206164
	H3301764
	H3323734
	H3342755
	H3372113
	H3385315
CENFT31K	H2821396
	H2884650
	H2900615
	H2911536
	H2933865
	H2971861
	H3003224
	H3059059
	H3059060
	H3089477
	H3101838
CENFT31K/A	H2938653
	H3013843
CENFT31K/B	H2811536
CENFT31K/D	H3071085
	H3071309
	H3082414
	H3144317
	H3163092
	H3179823
	H3191620
	H3206153
	H3239916
	H3249277
	H3275168
	H3283445
	H3306075
	H3323741
DC0145550/C	H2600169

Catalog Code	Lot Number
	I3085060
	I3173615
	I3178896
	I3195157
H787103028185/A	I3288651
	I3334629
H787103028191/A	I2909758
H787103028195/A	I2890957
	I2929321
	I3021395
	I3049573
	I3076853
	I3124837
	I3169030
	I3213148
	I3236141
	I3236161
	I3302447
	I3343042
H787103028205/A	I2927146
	I2995766
	I3015801
	I3044846
	I3144026
	I3219464
	I3288564
	I3302448
H787103028215/A	I3178904
H787103028225/A	I3044836
	I3108157
	I3236142
	I3315958
DC21452419/C	H2659228
DC21452419-NE5/C	H3249278
DC21452823/C	H2600164
	H2628890
DC21452823-NE5/C	H2990807

Catalog Code	Lot Number
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