URGENT FIELD SAFETY NOTICE/ DEVICE RECALL

20/30 INDEFLATOR™, INDEFLATOR™ Plus 30 and Priority Packs

Commercial Name:
20/30 INDEFLATOR™ Inflation Device
20/30 Priority Pack Accessory Kit
INDEFLATOR™ PLUS 30
Plus 30 Priority Pack Accessory Kit

FSCA-Identifier: INDEFLATORS & PPacks March 11, 2022
Manufacturer: Abbott Vascular Santa Clara SRN# US-MF-000003850
Type of Action: Device Recall

Attention: Risk Manager or Healthcare Professional

Dear Valued Abbott Customer:

Abbott has initiated a field action for specific lots of 20/30 INDEFLATOR™, INDEFLATOR™ Plus 30 and associated Priority Packs. Our records indicate that affected devices have been shipped to your account.

This action does not affect patients having successfully undergone procedures using these devices.

Devices from these lots may exhibit leaks and/or a loose connection at the rotating luer assembly or stopcock connection, which could lead to air ingress under vacuum. Analysis indicates an estimated rate of occurrence of air ingress associated with the device is 0.4%. While no long-term adverse patient effects have been attributed to this issue, potential risks include air embolism, thrombosis and foreign body in patient.

What action should you to take?

- Immediately stop using devices from affected lots (see attached)
- Review your inventory, complete and return the provided Effectiveness Check Form
- Return all unused affected devices to Abbott
- Share this notification with relevant personnel in your organization
- Report any occurrence of product performance issues or patient adverse events to Abbott

What action is Abbott taking?

- Abbott has taken immediate action to stop shipping devices from affected lots.
- The investigation has determined there are no other affected products or lots in distribution.
- Abbott will implement appropriate corrective actions to ensure product performance.
- Abbott will work with you to replace inventory, when available.
- The appropriate regulatory agencies have been notified of this action.

We regret any inconvenience this may cause you and appreciate your patience. Abbott is committed to providing high quality, compliant products and ensuring customer satisfaction. If you have any questions, please do not hesitate to contact your local Abbott Representative or Customer Service department.

Sincerely,

<signature of country manager>
<printed name>

Part Numbers and Lot Numbers

Device Identifier/GTIN	Device Description	Part Number	Lot Number		
08717648013591	20/30 INDEFLATOR	1000184	60309678	60315914	60331726
			60311336	60317535	60331727
			60311337	60317539	60334491
			60311338	60318209	60334492
			60311339	60320071	60337162
			60315913	60320899	60337166
08717648013614	20/30 Priority Pack Accessory Kit/.096 RHV	1000186	60317536	60320910	60334116
			60317537	60320911	60338482
			60317542	60325409	60338488
			60318666	60326622	60338489
			60320079	60326623	
			60320909	60329936	
08717648015274	20/30 Priority Pack Kit/.115 RHV	1000186-115	60311340	60318663	60329334
			60311346	60318664	60334117
			60317538	60318665	60334737
			60318661	60318667	
			60318662	60325410	
08717648013973	20/30 Priority Pack Accessory Kit w/Copilot	1003327	60308571	60316407	60325101
			60308572	60317004	60325103
			60308573	60317279	60326298
			60308574	60317280	60326299
			60308575	60317533	60326300
			60309671	60317540	60326301
			60309672	60317541	60326425
			60309673	60317947	60326859
			60309674	60317948	60326860
			60309675	60318668	60326861
			60309676	60318669	60326862
			60309677	60318670	60326863
			60309681	60319819	60328011
			60309682	60320067	60328023
			60309683	60320068	60328355
			60309684	60320069	60328356
			60309685	60320070	60329330
			60309686	60320072	60329331
			60309687	60320073	60329332
			60311341	60320074	60329333
				60320075	60329967

Device Identifier/GTIN	Device Description	Part Number	Lot Number		
08717648013973	20/30 Priority Pack Accessory Kit w/Copilot	1003327	60311342	60320076	60329968
			60311343	60320914	60329969
			60311344	60322147	60330058
			60311345	60322182	60331041
			60312167	60322183	60331042
			60312168	60322184	60331043
			60312169	60322185	60331358
			60312170	60323316	60331537
			60312171	60323317	60331538
			60312172	60323318	60331731
			60312173	60323319	60331733
			60312174	60323320	60331943
			60312175	60323321	60334120
			60312176	60323322	60334121
			60312177	60323323	60334122
			60312178	60323324	60334123
			60313415	60323325	60334449
			60313416	60323434	60335132
			60313417	60323785	60335214
			60313418	60323786	60335817
			60313420	60323787	60336487
			60313421	60325097	60337158
			60313422	60325098	60337397
			60315918	60325099	
			60315919	60325100	
08717648013584	PLUS 30 INDEFLATOR	1000183	60312165	60320908	60327731
			60313282	60320913	60328010
			60313413	60322176	60328352
			60315909	60322179	60333403
			60316775	60326322	60337153
			60320904	60326865	60337157
			60320905	60326866	60338458
			60320906	60326867	60338479
8717648013607	Plus 30 Priority Pack 0.096	1000185	60312166	60317532	60326601
			60313414	60323313	60329935
			60315910	60323314	60337154
08717648015267	Plus 30 Priority Pack 0.115	1000185-115	60316763	60323315	

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Effectiveness Check Form

Customer Account # _____

Account Name _____

Address _____

_____

(Information required for regulatory effectiveness check)

After reviewing your inventory for the affected devices, complete this form and return this form and any affected devices to Abbott per the instructions below.

Check One:

☐ A thorough search for all affected devices has been completed and no affected units remain in inventory. **No devices will be returned.**

☐ Affected devices have been identified and are being returned

RGA Number: _____

_____ _____ _____
Customer Name/ Job Title (print) ***Signature*** ***Date***

This form is to be returned to Abbott

- If returning product, call Customer Service <insert phone number> to receive RGA number. Record RGA number above.

Scan and email this form to <insert email> *or* fax to <insert phone number>

- Return a copy of this completed form with the returned product.