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	60320071	60337162
			60311336	60320899	60337166
			60311338	60331726	60311337
			60311339	60331727	60317539
			60315914	60334491	60318209
			60317535	60334492	
08717648013614	20/30 Priority Pack Accessory Kit/.096 RHV	1000186	60317536	60320079	60325409
			60317537	60320909	60326623
			60317542	60320910	60329936
			60318666	60320911	60334116
08717648015274	20/30 Priority Pack Kit/.115 RHV	1000186-115	60311340	60318662	60329334
			60311346	60318663	60334117
			60317538	60318664	60334737
			60318661	60318665	
08717648013973	20/30 Priority Pack Accessory Kit w/Copilot	1003327	60308571	60315919	60325098
			60308572	60316407	60325099
			60308573	60317004	60325100
			60308574	60317279	60325101
			60308575	60317280	60325103
			60309671	60317533	60326298
			60309672	60317540	60326299
			60309673	60317541	60326300
			60309674	60317947	60326301
			60309675	60317948	60326425
			60309676	60318668	60326859
			60309677	60318669	60326860
			60309681	60318670	60326861
			60309682	60319819	60326862
			60309683	60320067	60326863
			60309684	60320068	60328011
			60309685	60320069	60328023
			60309686	60320070	60328355
			60309687	60320072	60328356
			60311341	60320073	60329330
			60311342	60320074	60329331

Device Identifier/GTIN	Device Description	Part Number	Lot Number
08717648013973	20/30 Priority Pack Accessory Kit w/Copilot	1003327	60311343 60320075 60329332 60311344 60320076 60329333 60311345 60320914 60329967 60312167 60322147 60329968 60312168 60322182 60329969 60312169 60322183 60330058 60312170 60322184 60331041 60312171 60322185 60331043 60312172 60323316 60331358 60312173 60323317 60331537 60312174 60323318 60331538 60312175 60323319 60331731 60312176 60323320 60331733 60312177 60323321 60331943 60312178 60323322 60334120 60313415 60323323 60334121 60313416 60323324 60334122 60313417 60323325 60334123 60313418 60323434 60335132 60313420 60323785 60335817 60313421 60323786 60336487 60313422 60323787 60337158 60315918 60325097
08717648013584	PLUS 30 INDEFLATOR	1000183	60316775 60322179 60328352 60322176 60326322 60337153
08717648013607	Plus 30 Priority Pack 0.096	1000185	60317532 60323314 60329935 60323313 60326601
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.