FSCA Ref: 632673

Customer Reply Form
Field Safety Notice

1. Field Safety Notice (FSN) information	
FSN Reference number*	632673
FSN Date*	28/10/2026
Product/ Device name*	5000000 - 22mm Smoothbore breathing system, ≥ 1.6m 5000012 - 22mm Smoothbore breathing system with 2L bag, and bagging limb, ≥ 1.8m 5000019 - 22mm Smoothbore breathing system with 2L bag, and limb, ≥ 2m 5000022 - 22mm Smoothbore breathing system with 2L bag, luer elbow, and limb, ≥ 1.5m 5000034 - 22mm Smoothbore breathing system. ≥ 3.2m 5000039 - 22mm SMOOTHBORE SYSTEM, 1M LIMB, 2L RESERVOIR BAG, 2.4M 5000064 - 22mm Smoothbore breathing system with 2 L bag, luer connector, and bagging limb, ≥ 3.0m 5000190 - 22mm Smoothbore breathing system. ≥ 1.6m 5001000 - 22mm Smoothbore breathing system, ≥ 2.0m 5001000S - 22mm Smoothbore breathing system, ≥ 2m - sterile 5003000 - 22mm Smoothbore tube with soft end connectors, 22F-22F, 0.3m 5004000 - 22mm Smoothbore tube with soft end connectors, 22F-22F, 0.4m 5005000 - 22mm Smoothbore tube with soft end connectors, 22F-22F, 0.5m 5006000 - 22mm Smoothbore tube with soft end connectors, 22F-22F, ≥ 0.6m 5007000 - 22mm Smoothbore breathing system with water trap and ported Y-piece, ≥1.6m 5007000S - 22mm Smoothbore breathing system with water trap and ported Y-piece, ≥1.6m - sterile 5007001 - 22mm Smoothbore breathing system with water trap and ported y-piece. ≥ 2.0m 5007002 - 22mm Smoothbore breathing system with water trap, ported y-piece and extra limb. ≥ 1.5m 5007003 - 22mm Smoothbore breathing system with water trap, ≥ 1.5m 5007004 - 22mm Smoothbore breathing system with water trap, ported y-piece and extra limb. ≥ 1.5m 5007005 - 22mm Smoothbore breathing system with extra limb. ≥ 1.5m 5007006 - 22mm Smoothbore breathing system with water trap and extra limb. ≥ 2.0m 5007009 - 22mm Smoothbore breathing system with 2L bag, single water trap, and bagging limb, ≥ 1.5m 5007010 - 22mm Smoothbore breathing system with 2L bag, single water trap, and bagging limb, ≥ 2.4m 5007011 - 22mm Smoothbore breathing system with 2L bag, single water trap, and bagging limb, ≥ 3.2m 5007012 - 22mm Smoothbore breathing system with 2L bag, single water trap, and bagging limb, ≥ 4m 5008000 - 22mm Smoothbore breathing system with water traps and ported Y-piece, ≥1.6m

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	5008001 - 22mm Smoothbore breathing system with water trap and ported y-piece. ≥ 2.0m 5008002 - 22mm Smoothbore breathing system with water traps and ported y-piece. ≥ 2.6m 5008003 - 22mm Smoothbore Breathing system with water traps ≥ 3.0m 5008006 - 22mm Smoothbore breathing system with 2 L bag, luer elbow, water traps, and bagging limb, ≥ 1.5m 5008019 - 22mm Smoothbore breathing system with 2 L bag, elbow, monitoring line, water traps, and limb, ≥ 2.8m 5009000 - 22mm Smoothbore breathing system with water traps, ported Y-piece and extra limb, ≥ 1.6m 5009000S - 22mm Smoothbore breathing system with water traps, ported y-piece and extra limb, ≥ 1.6m sterile 5009001 - 22mm Smoothbore breathing system with water traps and 0.5m limb, ≥ 2m 5009002 - 22mm Smoothbore breathing system with water traps and extra limb. ≥ 1.5m 5009003 - 22mm Smoothbore breathing system with water traps and extra limb. ≥ 1.6m 5009004 - 22mm Smoothbore breathing system with water traps and extra limb. ≥ 2.0m 5009005 - 5009005, SMOOTHBORE BREATHING SYSTEM 2.5M, LIMB 1M, WATER TRAPS 5009006 - 22mm Smoothbore breathing system with water traps and 1.0m limb. ≥ 3.0m 5009007 - 22mm Smoothbore breathing system with 2L bag, water traps, and bagging limb, ≥ 2m 5009009 - 15mm Smoothbore breathing system with water traps and 1m limb, 2m 5009011 - 22mm Smoothbore breathing system with 2L bag, water traps, and bagging limb, ≥ 1.6m 5009022 - 22mm Smoothbore breathing system with 2 L bag, luer elbow, water traps, and limb, ≥ 2.0m 5009033S - 22mm Smoothbore breathing system with water traps, ported Y-piece and extra limb, ≥ 1.8m - sterile 5009034S - 22mm Smoothbore breathing system with water traps and extra limb, ≥ 1.8m - sterile 5009039 - 22mm Smoothbore breathing system with 2 L bag, elbow, monitoring line, water traps, and limb, ≥ 2.0m 5009044 - 22mm Smoothbore breathing system with 2L bag, water traps, and bagging limb, ≥ 2.5m 5009068 - 22mm Smoothbore breathing system with 2L bag, luer elbow, monitoring line, water traps, and limb, ≥ 2m 5009190 - 22mm SM/B B/S EXTRA LIMB >= 1.5M 5010000 - 22mm Smoothbore tube with soft end connectors, 22F-22F, ≥ 1.0m 5011000 - 22mm Smoothbore breathing system with 2 L bag, luer elbow and limb, ≥ 1.8m 5011001S - 22mm Smoothbore breathing system with 2L bag, luer elbow, and limb, ≥ 1.8m sterile 5011005 - 22mm Smoothbore breathing system with 2L bag, luer elbow, and limb, ≥ 2.4m 5012000 - 22mm Smoothbore tube with soft end connectors, 22F-22F, ≥ 1.2m

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	5013005 - 22mm Smoothbore exhalation valve breathing system with control line and monitoring line (removable). ≥ 1.6m 5013018 - 22mm Smoothbore exhalation valve breathing system with control line. ≥ 1.6m 5013019 - 22mm Smoothbore breathing system with water traps and swivel y-piece. ≥ 1.6m 5015000 - 5015000, 22mm Smoothbore tube with soft end connectors, 22F-22F, ≥ 1.5m 5015004 - 22mm Smoothbore bagging limb with 2 L bag, ≥ 1.5m 5018000 - 22mm Smoothbore tube with soft end connectors, 22F-22F, ≥ 1.8m 5018000S - 22mm Smoothbore tube with soft end connectors, 22F-22F, ≥1.8m - sterile 5018012 - 22mm Smoothbore cough assist, breathing system with Flo-Guard™ filter. ≥ 1.8m 5018013 - 22mm Smoothbore breathing system with O_2 tubing and Flo-Guard™ filter, ≥ 1.8m 5020000 - 22mm Smoothbore tube with soft end connectors, 22F-22F, 2.0m 5020000S - 22mm Smoothbore tube with soft end connectors, 22F-22F, 2.0m - sterile 5020002 - 22mm Smoothbore transport breathing system. ≥ 2.0m 5025000 - 22mm Smoothbore single heated wire breathing system with water trap, ≥ 1.6m 5025310 - 22mm Smoothbore single heated wire breathing system with water trap and auto-fill chamber, ≥ 1.6m 5025310S - 22mm Smoothbore single heated wire breathing system with water trap and auto-fill chamber, ≥ 1.6m -sterile 5026000 - 22mm Smoothbore dual heated wire breathing system, ≥ 1.6m 5026310 - 22mm Smoothbore dual heated wire breathing system with auto-fill chamber, ≥ 1.6m 5080000 - 22mm Smoothbore tube with soft end connectors, 22F-22F, 0.8m 5083008 - 22mm SM/B EX/VALVE B/S C/LINE M/LINE F >= 1.6M 5113006 - 22mm Smoothbore breathing system with pressure monitoring kit and water trap, with 0.4m limb, ≥ 1.6m 5113010 - 22mm Smoothbore breathing system with monitoring line, water trap and exhalation valve and 0.4m limb, ≥ 1.6m 5113020 - 22mm Smoothbore exhalation valve dual limb breathing system with monitoring line and water trap. ≥ 1.6m 5183000 - 22mm Smoothbore breathing system with monitoring line and exhalation valve, ≥ 1.6m 5183001 - 22mm Smoothbore exhalation valve breathing system with monitoring line. ≥ 1.8m 5190009 - 22mm Smoothbore exhalation valve breathing system. ≥ 1.8m 5191000 - 22mm Smoothbore breathing system with monitoring line and exhalation valve, single limb, 1.8m 5191004 - 22mm Smoothbore breathing system with exhalation valve, ≥ 1.8m 5191045 - 22mm Smoothbore exhalation valve breathing system. ≥ 0.6m 5191160 - 22mm Smoothbore exhalation valve breathing system with monitoring line. ≥ 1.8m 5191170 - 22mm Smoothbore exhalation valve breathing system with monitoring line, water trap and extra limb. ≥ 1.6m 5191172 - 22mm Smoothbore exhalation valve breathing system with monitoring line with filter, water trap, extra limb and Flo-Guard™ filter. ≥ 1.8m

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	5191175 - 22mm Smoothbore exhalation valve breathing system with monitoring line (removable) and Flo-Guard™ filter. ≥ 1.8m 5191176 - 22mm Smoothbore exhalation valve breathing system with monitoring line (removable) with filter, water trap, extra limb and Flo-Guard™ filter. ≥ 1.6m 5191850 - 22mm Smoothbore exhalation valve heated wire breathing system with monitoring line and extra limb. ≥ 1.6m 5191852 - 22mm Smoothbore exhalation valve heated wire breathing system with monitoring line and extra limb. ≥ 1.6m 5191855 - 22mm Smoothbore exhalation valve heated wire breathing system with monitoring line, Flo-Guard and extra limb. ≥ 1.6m 5192000 - 22mm Smoothbore exhalation valve dual limb breathing system with monitoring line and water trap. ≥ 1.8m 5194000 - 22mm Smoothbore exhalation valve breathing system. ≥ 1.8m 5194006 - 22mm S/BORE B/SYS, EXHALATION VALVE, 1.5M 5194190 - 22mm Smoothbore exhalation valve breathing system with water trap and extra limb. ≥ 1.6m 5194850 - 22mm Smoothbore exhalation valve heated wire breathing system with extra limb. ≥ 1.6m 5196000 - 22mm Smoothbore exhalation valve breathing system with monitoring line. ≥ 1.8m 5197000 - 22mm Smoothbore single limb breathing system with monitoring line and exhalation valve, 1.8m 5197001 - 22mm Smoothbore exhalation valve breathing system limb with monitoring line with filter, water trap, extra limb and Flo-Guard™ filter. ≥ 1.8m 5803000 - 22mm SM/B BILEVEL B/S SWVL/CON >= 1.8M 5804000 - 22mm Smoothbore bilevel breathing system with swivel CO_2 leak port, ≥ 1.8m 5804011 - 22mm Smoothbore bilevel breathing system with swivel CO_2 leak port and Flo-Guard™ filter, ≥ 1.8m 5804855 - 22mm SM/B BILEVEL H/W CO2 L/PORT FLOGUARD 7 LIMB >= 1.6M 5805000 - 22mm Smoothbore bilevel breathing system with monitoring line and swivel CO_2 leak port, ≥ 1.6m 5805003 - 22mm Smoothbore bilevel breathing system with monitoring line, swivel CO_2 leak port, extra limb and Flo-Guard™ filter. ≥ 1.6m 5805006 - 22mm Smoothbore bilevel breathing system with monitoring line, swivel CO_2 leak port and Flo-Guard™ filter. ≥ 2.0m 5805030 - 22mm Smoothbore bilevel breathing system with swivel CO2 leak port and Clear-Guard Midi filter, ≥ 1.8m 5805031 - 22mm Smoothbore bilevel breathing system with swivel CO2 leak port and monitoring line. ≥ 1.8m 5805044 - 22mm Smoothbore bilevel breathing system with monitoring line, swivel CO_2 leak port and Flo-Guard™ filter, ≥ 1.8m 5805175 - 22mm Smoothbore bilevel breathing system with monitoring line, swivel CO_2 leak port and Flo-Guard™ filter. ≥ 1.6m 5808005 - 22mm Smoothbore bilevel heated wire breathing system with swivel CO_2 leak port, auto-fill chamber, Clear-Guard™ and extra limb. ≥ 1.6m 5809130 - 22mm Smoothbore bilevel breathing system with monitoring line with filter, water trap, swivel CO_2 leak port and extra limb. ≥ 1.6m 5809176 - 22mm Smoothbore bilevel breathing system with water trap, swivel CO_2 leak port and extra limb. ≥ 1.8m

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	5819002 - 22mm Smoothbore bilevel breathing system for use with the NKV-330™ ventilator, with monitoring line, water trap, swivel CO_2 leak port and Flo-Guard filter, ≥ 1.6 m 5825000 - 22mm Smoothbore bilevel breathing system with monitoring line and swivel patient connector, ≥ 1.6m RM21301 - 22mm SMOOTHBORE SYSTEM, WATER TRAPS, 1.8M RM21303 - 22mm SMOOTHBORE DUAL LIMB CIRCUIT 1.8M RM21311 - 22mm SMOOTHBORE WITH EXHALATION VALVE, 1.8M RM21313 - 22mm S/BORE S/LIMB CIRCUIT EXHALATION VALVE, 0.5M LIMB, 1.8M
Product Code(s)	5000000, 5000012, 5000019, 5000022, 5000034, 5000039, 5000064, 5000190, 5001000, 5001000S, 5003000, 5004000, 5005000, 5006000, 5007000, 5007000S, 5007001, 5007002, 5007003, 5007004, 5007005, 5007006, 5007009, 5007010, 5007011, 5007012, 5008000, 5008001, 5008002, 5008003, 5008006, 5008019, 5009000, 5009000S, 5009001, 5009002, 5009003, 5009004, 5009005, 5009006, 5009007, 5009009, 5009011, 5009022, 5009033S, 5009034S, 5009039, 5009044, 5009068, 5009190, 5010000, 5011000, 5011001S, 5011005, 5012000, 5013005, 5013018, 5013019, 5015000, 5015004, 5018000, 5018000S, 5018012, 5018013, 5020000, 5020000S, 5020002, 5025000, 5025310, 5025310S, 5026000, 5026310, 5080000, 5083008, 5113006, 5113010, 5113020, 5183000, 5183001, 5190009, 5191000, 5191004, 5191045, 5191160, 5191170, 5191172, 5191175, 5191176, 5191850, 5191852, 5191855, 5192000, 5194000, 5194006, 5194190, 5194850, 5196000, 5197000, 5197001, 5803000, 5804000, 5804011, 5804855, 5805000, 5805003, 5805006, 5805030, 5805031, 5805044, 5805175, 5808005, 5809130, 5809176, 5819002, 5825000, RM21301, RM21303, RM21311, RM21313.
Batch/Serial Number (s)	1. **Affected lot numbers.** All lot numbers as listed below next to the device catalogue (product) reference number. 1. Affected lot numbers. All lot numbers as listed below next to the device catalogue (product) reference number. 5000000 - 32521727; 32527291. 5000012 - 32504855; 32510565; 32513089; 32517505; 32523060; 32526688. 5000019 - 32507679; 32509753; 32514485; 32514542; 32520382; 32521349; 32523077; 32523770; 32526107; 32526689. 5000022 - 32505971; 32507363; 32511150; 32511259; 32512803; 32513453; 32517384; 32520672; 32521164; 32525556. 5000034 - 32504698; 32507785; 32509091; 32513454; 32516094; 32525501; 32527771. 5000039 - 32500600; 32502810; 32512576; 32516601; 32520881; 32520961; 32524212; 32524777. 5000064 - 32504798; 32505806; 32507713; 32512030; 32512398; 32521337; 32524506; 32525538; 32528403. 5000190 - 32516316. 5001000 - 32500013; 32500312; 32500559; 32501452; 32501690; 32502363; 32502521; 32503197; 32503645; 32504162; 32504703; 32504892; 32505575; 32505870; 32507048; 32507487; 32508055; 32508714; 32508904; 32509124; 32509515; 32510526; 32511325; 32512128; 32512529; 32513168; 32513331; 32513761; 32513956; 32514904; 32515332; 32515235; 32515663; 32516181; 32516634; 32516904; 32517342; 32517650; 32517966; 32518770; 32519579; 32519987; 32520055; 32521427; 32521898; 32522118; 32522466; 32522724; 32522992; 32523210; 32523457; 32525139; 32525477; 32526827; 32527379; 32528288. 5001000S - 32506950; 32511800; 32519577; 32522232.

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2. Customer Details	
Account Number	
Healthcare Organisation Name*	
Organisation Address*	
Department/Unit	
Contact Name*	
Title or Function	
Telephone number*	
Email*	

3. Customer action undertaken on behalf of Healthcare Organisation					
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	Customer to complete or enter N/A			
☐	The information and required actions have been brought to the attention of all relevant users and executed.	Customer to complete or enter N/A			
☐	I do not have any affected devices.	Customer to complete or enter N/A			
☐	We have the following potentially affected stock we wish to return for credit/replacement. (Please enter the quantity for each Code and Lot number).	**Code:**	**Lot:**	**Qty:**	
		Code:	**Lot:**	**Qty:**	
		Code:	**Lot:**	**Qty:**	
		Code:	**Lot:**	**Qty:**	
		Code:	**Lot:**	**Qty:**	
☐	Any Other comments:				
Print Name*		Customer print name here			
Signature*		Customer sign here			
Date*					

4. Return acknowledgement to sender	
Email	
Customer Helpline	
Postal Address	
Web Portal	
Deadline for returning the customer reply form*	

Mandatory fields are marked with *

FSCA Ref: 632673

A “Field Safety Notice” (FSN) is an important communication about the safety of a medical device that is sent to customers by Intersurgical.
The FSN informs you of the actions you need to take to reduce the specified risks of using the medical device. It provides additional information and may reinforce existing advice. The actions are referred to as “Field Safety Corrective Actions” (FSCA). If you receive a Field Safety Notice from Intersurgical, **please always act on it immediately** and do not wait for a communication from the Competent Authority.
It is important that your organisation confirms that you have received the FSN and are taking the actions detailed in the FSN.
Your organisation's reply is the evidence required by both, Intersurgical and the Competent Authority to monitor the progress of the corrective actions to ensure patient safety.