**FSCA Ref: 632673**

**FSCA Date: 28/10/2026**

# Urgent Field Safety Notice

## SMOOTHBORE BREATHING SYSTEMS

For Attention of*: MDSO's, All clinical staff, Managers and users of the above products

| Contact details of local representative (name, e-mail, telephone, address etc.)* |
|---|
| **Giedrius Budrys**<br>**Group Customer Resolution and Relationship Manager**<br>**Intersurgical UAB**<br>**Arnioniu str 60, LT-18170 Pabrade Lithuania**<br><br>**Email: giedriusb@intersurgical.lt**<br>**Tel. +370 387 66611**<br><br>**or**<br><br>**This could be a distributor or local branch of the manufacturer. To be added at the appropriate stage in the different local languages** |

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## Urgent Field Safety Notice (FSN)

## SMOOTHBORE BREATHING SYSTEMS

## Risk addressed by FSN

# FSCA Ref: 632673

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|---|---|
| | **1. Information on Affected Devices*** |
| 1. | **1. Device Type(s)*** |
| | **Smoothbore Breathing Systems** |
| 1. | **2. Commercial name(s)** |
| | **5000000 - 22mm Smoothbore breathing system, ≥ 1.6m**<br>**5000012 - 22mm Smoothbore breathing system with 2L bag, and bagging limb, ≥ 1.8m**<br>**5000019 - 22mm Smoothbore breathing system with 2L bag, and limb, ≥ 2m**<br>**5000022 - 22mm Smoothbore breathing system with 2L bag, luer elbow, and limb, ≥ 1.5m**<br>**5000034 - 22mm Smoothbore breathing system. ≥ 3.2m**<br>**5000039 - 22mm SMOOTHBORE SYSTEM, 1M LIMB, 2L RESERVOIR BAG, 2.4M**<br>**5000064 - 22mm Smoothbore breathing system with 2 L bag, luer connector, and bagging limb, ≥ 3.0m**<br>**5000190 - 22mm Smoothbore breathing system. ≥ 1.6m**<br>**5001000 - 22mm Smoothbore breathing system, ≥ 2.0m**<br>**5001000S - 22mm Smoothbore breathing system, ≥ 2m - sterile**<br>**5003000 - 22mm Smoothbore tube with soft end connectors, 22F-22F, 0.3m**<br>**5004000 - 22mm Smoothbore tube with soft end connectors, 22F-22F, 0.4m**<br>**5005000 - 22mm Smoothbore tube with soft end connectors, 22F-22F, 0.5m**<br>**5006000 - 22mm Smoothbore tube with soft end connectors, 22F-22F, ≥ 0.6m**<br>**5007000 - 22mm Smoothbore breathing system with water trap and ported Y-piece, ≥1.6m**<br>**5007000S - 22mm Smoothbore breathing system with water trap and ported Y-piece, ≥1.6m - sterile**<br>**5007001 - 22mm Smoothbore breathing system with water trap and ported y-piece. ≥ 2.0m**<br>**5007002 - 22mm Smoothbore breathing system with water trap, ported y-piece and extra limb. ≥ 1.5m**<br>**5007003 - 22mm Smoothbore breathing system with water trap, ≥ 1.5m**<br>**5007004 - 22mm Smoothbore breathing system with water trap, ported y-piece and extra limb. ≥ 1.5m**<br>**5007005 - 22mm Smoothbore breathing system with extra limb. ≥ 1.5m**<br>**5007006 - 22mm Smoothbore breathing system with water trap and extra limb. ≥ 2.0m**<br>**5007009 - 22mm Smoothbore breathing system with 2L bag, single water trap, and bagging limb, ≥ 1.5m**<br>**5007010 - 22mm Smoothbore breathing system with 2L bag, single water trap, and bagging limb, ≥ 2.4m**<br>**5007011 - 22mm Smoothbore breathing system with 2L bag, single water trap, and bagging limb, ≥ 3.2m**<br>**5007012 - 22mm Smoothbore breathing system with 2L bag, single water trap, and bagging limb, ≥ 4m**<br>**5008000 - 22mm Smoothbore breathing system with water traps and ported Y-piece, ≥1.6m**<br>**5008001 - 22mm Smoothbore breathing system with water trap and ported y-piece. ≥ 2.0m**<br>**5008002 - 22mm Smoothbore breathing system with water traps and ported y-piece. ≥ 2.6m**<br>**5008003 - 22mm Smoothbore Breathing system with water traps ≥ 3.0m**<br>**5008006 - 22mm Smoothbore breathing system with 2 L bag, luer elbow, water traps, and bagging limb, ≥ 1.5m**<br>**5008019 - 22mm Smoothbore breathing system with 2 L bag, elbow, monitoring line, water traps, and limb, ≥ 2.8m**<br>**5009000 - 22mm Smoothbore breathing system with water traps, ported Y-piece and extra limb, ≥ 1.6m** |

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| | **5009000S - 22mm Smoothbore breathing system with water traps, ported y-piece and extra limb, ≥ 1.6m sterile**<br>**5009001 - 22mm Smoothbore breathing system with water traps and 0.5m limb, ≥ 2m**<br>**5009002 - 22mm Smoothbore breathing system with water traps and extra limb. ≥ 1.5m**<br>**5009003 - 22mm Smoothbore breathing system with water traps and extra limb. ≥ 1.6m**<br>**5009004 - 22mm Smoothbore breathing system with water traps and extra limb. ≥ 2.0m**<br>**5009005 - 5009005, SMOOTHBORE BREATHING SYSTEM 2.5M, LIMB 1M, WATER TRAPS**<br>**5009006 - 22mm Smoothbore breathing system with water traps and 1.0m limb. ≥ 3.0m**<br>**5009007 - 22mm Smoothbore breathing system with 2L bag, water traps, and bagging limb, ≥ 2m**<br>**5009009 - 15mm Smoothbore breathing system with water traps and 1m limb, 2m**<br>**5009011 - 22mm Smoothbore breathing system with 2L bag, water traps, and bagging limb, ≥ 1.6m**<br>**5009022 - 22mm Smoothbore breathing system with 2 L bag, luer elbow, water traps, and limb, ≥ 2.0m**<br>**5009033S - 22mm Smoothbore breathing system with water traps, ported Y-piece and extra limb, ≥ 1.8m - sterile**<br>**5009034S - 22mm Smoothbore breathing system with water traps and extra limb, ≥ 1.8m - sterile**<br>**5009039 - 22mm Smoothbore breathing system with 2 L bag, elbow, monitoring line, water traps, and limb, ≥ 2.0m**<br>**5009044 - 22mm Smoothbore breathing system with 2L bag, water traps, and bagging limb, ≥ 2.5m**<br>**5009068 - 22mm Smoothbore breathing system with 2L bag, luer elbow, monitoring line, water traps, and limb, ≥ 2m**<br>**5009190 - 22mm SM/B B/S EXTRA LIMB >= 1.5M**<br>**5010000 - 22mm Smoothbore tube with soft end connectors, 22F-22F, ≥ 1.0m**<br>**5011000 - 22mm Smoothbore breathing system with 2 L bag, luer elbow and limb, ≥ 1.8m**<br>**5011001S - 22mm Smoothbore breathing system with 2L bag, luer elbow, and limb, ≥ 1.8m sterile**<br>**5011005 - 22mm Smoothbore breathing system with 2L bag, luer elbow, and limb, ≥ 2.4m**<br>**5012000 - 22mm Smoothbore tube with soft end connectors, 22F-22F, ≥ 1.2m**<br>**5013005 - 22mm Smoothbore exhalation valve breathing system with control line and monitoring line (removable). ≥ 1.6m**<br>**5013018 - 22mm Smoothbore exhalation valve breathing system with control line. ≥ 1.6m**<br>**5013019 - 22mm Smoothbore breathing system with water traps and swivel y-piece. ≥ 1.6m**<br>**5015000 - 5015000, 22mm Smoothbore tube with soft end connectors, 22F-22F, ≥ 1.5m**<br>**5015004 - 22mm Smoothbore bagging limb with 2 L bag, ≥ 1.5m**<br>**5018000 - 22mm Smoothbore tube with soft end connectors, 22F-22F, ≥ 1.8m**<br>**5018000S - 22mm Smoothbore tube with soft end connectors, 22F-22F, ≥1.8m - sterile**<br>**5018012 - 22mm Smoothbore cough assist, breathing system with Flo-Guard™ filter. ≥ 1.8m**<br>**5018013 - 22mm Smoothbore breathing system with $O_2$ tubing and Flo-Guard™ filter, ≥ 1.8m**<br>**5020000 - 22mm Smoothbore tube with soft end connectors, 22F-22F, 2.0m**<br>**5020000S - 22mm Smoothbore tube with soft end connectors, 22F-22F, 2.0m - sterile**<br>**5020002 - 22mm Smoothbore transport breathing system. ≥ 2.0m**<br>**5025000 - 22mm Smoothbore single heated wire breathing system with water trap, ≥ 1.6m**<br>**5025310 - 22mm Smoothbore single heated wire breathing system with water trap and auto-fill chamber, ≥ 1.6m**<br>**5025310S - 22mm Smoothbore single heated wire breathing system with water trap and auto-fill chamber, ≥ 1.6m -sterile**<br>**5026000 - 22mm Smoothbore dual heated wire breathing system, ≥ 1.6m** |

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| | **5026310 - 22mm Smoothbore dual heated wire breathing system with auto-fill chamber, ≥ 1.6m**<br>**5080000 - 22mm Smoothbore tube with soft end connectors, 22F-22F, 0.8m**<br>**5083008 - 22mm SM/B EX/VALVE B/S C/LINE M/LINE F >= 1.6M**<br>**5113006 - 22mm Smoothbore breathing system with pressure monitoring kit and water trap, with 0.4m limb, ≥ 1.6m**<br>**5113010 - 22mm Smoothbore breathing system with monitoring line, water trap and exhalation valve and 0.4m limb, ≥ 1.6m**<br>**5113020 - 22mm Smoothbore exhalation valve dual limb breathing system with monitoring line and water trap. ≥ 1.6m**<br>**5183000 - 22mm Smoothbore breathing system with monitoring line and exhalation valve, ≥ 1.6m**<br>**5183001 - 22mm Smoothbore exhalation valve breathing system with monitoring line. ≥ 1.8m**<br>**5190009 - 22mm Smoothbore exhalation valve breathing system. ≥ 1.8m**<br>**5191000 - 22mm Smoothbore breathing system with monitoring line and exhalation valve, single limb, 1.8m**<br>**5191004 - 22mm Smoothbore breathing system with exhalation valve, ≥ 1.8m**<br>**5191045 - 22mm Smoothbore exhalation valve breathing system. ≥ 0.6m**<br>**5191160 - 22mm Smoothbore exhalation valve breathing system with monitoring line. ≥ 1.8m**<br>**5191170 - 22mm Smoothbore exhalation valve breathing system with monitoring line, water trap and extra limb. ≥ 1.6m**<br>**5191172 - 22mm Smoothbore exhalation valve breathing system with monitoring line with filter, water trap, extra limb and Flo-Guard™ filter. ≥ 1.8m**<br>**5191175 - 22mm Smoothbore exhalation valve breathing system with monitoring line (removable) and Flo-Guard™ filter. ≥ 1.8m**<br>**5191176 - 22mm Smoothbore exhalation valve breathing system with monitoring line (removable) with filter, water trap, extra limb and Flo-Guard™ filter. ≥ 1.6m**<br>**5191850 - 22mm Smoothbore exhalation valve heated wire breathing system with monitoring line and extra limb. ≥ 1.6m**<br>**5191852 - 22mm Smoothbore exhalation valve heated wire breathing system with monitoring line and extra limb. ≥ 1.6m**<br>**5191855 - 22mm Smoothbore exhalation valve heated wire breathing system with monitoring line, Flo-Guard and extra limb. ≥ 1.6m**<br>**5192000 - 22mm Smoothbore exhalation valve dual limb breathing system with monitoring line and water trap. ≥ 1.8m**<br>**5194000 - 22mm Smoothbore exhalation valve breathing system. ≥ 1.8m**<br>**5194006 - 22mm S/BORE B/SYS, EXHALATION VALVE, 1.5M**<br>**5194190 - 22mm Smoothbore exhalation valve breathing system with water trap and extra limb. ≥ 1.6m**<br>**5194850 - 22mm Smoothbore exhalation valve heated wire breathing system with extra limb. ≥ 1.6m**<br>**5196000 - 22mm Smoothbore exhalation valve breathing system with monitoring line. ≥ 1.8m**<br>**5197000 - 22mm Smoothbore single limb breathing system with monitoring line and exhalation valve, 1.8m**<br>**5197001 - 22mm Smoothbore exhalation valve breathing system limb with monitoring line with filter, water trap, extra limb and Flo-Guard™ filter. ≥ 1.8m**<br>**5803000 - 22mm SM/B BILEVEL B/S SWVL/CON >= 1.8M**<br>**5804000 - 22mm Smoothbore bilevel breathing system with swivel $CO_2$ leak port, ≥ 1.8m**<br>**5804011 - 22mm Smoothbore bilevel breathing system with swivel $CO_2$ leak port and Flo-Guard™ filter, ≥ 1.8m**<br>**5804855 - 22mm SM/B BILEVEL H/W CO2 L/PORT FLOGUARD 7 LIMB >= 1.6M** |

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| | **5805000 - 22mm Smoothbore bilevel breathing system with monitoring line and swivel $CO_2$ leak port, ≥ 1.6m**<br>**5805003 - 22mm Smoothbore bilevel breathing system with monitoring line, swivel $CO_2$ leak port, extra limb and Flo-Guard™ filter. ≥ 1.6m**<br>**5805006 - 22mm Smoothbore bilevel breathing system with monitoring line, swivel $CO_2$ leak port and Flo-Guard™ filter. ≥ 2.0m**<br>**5805030 - 22mm Smoothbore bilevel breathing system with swivel CO2 leak port and Clear-Guard Midi filter, ≥ 1.8m**<br>**5805031 - 22mm Smoothbore bilevel breathing system with swivel CO2 leak port and monitoring line. ≥ 1.8m**<br>**5805044 - 22mm Smoothbore bilevel breathing system with monitoring line, swivel $CO_2$ leak port and Flo-Guard™ filter, ≥ 1.8m**<br>**5805175 - 22mm Smoothbore bilevel breathing system with monitoring line, swivel $CO_2$ leak port and Flo-Guard™ filter. ≥ 1.6m**<br>**5808005 - 22mm Smoothbore bilevel heated wire breathing system with swivel $CO_2$ leak port, auto-fill chamber, Clear-Guard™ and extra limb. ≥ 1.6m**<br>**5809130 - 22mm Smoothbore bilevel breathing system with monitoring line with filter, water trap, swivel $CO_2$ leak port and extra limb. ≥ 1.6m**<br>**5809176 - 22mm Smoothbore bilevel breathing system with water trap, swivel $CO_2$ leak port and extra limb. ≥ 1.8m**<br>**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**<br>**5825000 - 22mm Smoothbore bilevel breathing system with monitoring line and swivel patient connector, ≥ 1.6m**<br>**RM21301 - 22mm SMOOTHBORE SYSTEM, WATER TRAPS, 1.8M**<br>**RM21303 - 22mm SMOOTHBORE DUAL LIMB CIRCUIT 1.8M**<br>**RM21311 - 22mm SMOOTHBORE WITH EXHALATION VALVE, 1.8M**<br>**RM21313 - 22mm S/BORE S/LIMB CIRCUIT EXHALATION VALVE, 0.5M LIMB, 1.8M** |

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| 1. | 3. Unique Device Identifier(s) (UDI-DI) |
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| | **5000000 - 5030267068128.**<br>**5000012 - 5030267068241.**<br>**5000019 - 5030267088980.**<br>**5000022 - 5030267095339.**<br>**5000034 - 5030267117475.**<br>**5000039 - 5030267134120.**<br>**5000064 - 5030267152315.**<br>**5000190 - 5030267112586.**<br>**5001000 - 5030267068265.**<br>**5001000S - 5030267081431.**<br>**5003000 - 5030267068289.**<br>**5004000 - 5030267068296.**<br>**5005000 - 5030267068319.**<br>**5006000 - 5030267068333.**<br>**5007000 - 5030267068340.**<br>**5007000S - 5030267078622.**<br>**5007001 - 5030267068357.**<br>**5007002 - 5030267068364.**<br>**5007003 - 5030267068371.**<br>**5007004 - 5030267068388.**<br>**5007005 - 5030267068395.**<br>**5007006 - 5030267068401.**<br>**5007009 - 5030267117390.**<br>**5007010 - 5030267117437.**<br>**5007011 - 5030267117499.**<br>**5007012 - 5030267117413.**<br>**5008000 - 5030267068425.**<br>**5008001 - 5030267068432.**<br>**5008002 - 5030267068449.**<br>**5008003 - 5030267068456.**<br>**5008006 - 5030267068487.**<br>**5008019 - 5030267119424.**<br>**5009000 - 5030267068494.**<br>**5009000S - 5030267078646.**<br>**5009001 - 5030267068500.**<br>**5009002 - 5030267068517.**<br>**5009003 - 5030267068524.**<br>**5009004 - 5030267068531.**<br>**5009005 - 5030267068548.**<br>**5009006 - 5030267068555.**<br>**5009007 - 5030267068562.**<br>**5009009 - 5030267068586.**<br>**5009011 - 5030267068609.**<br>**5009022 - 5030267086030.**<br>**5009033S - 5030267104321.**<br>**5009034S - 5030267104383.**<br>**5009039 - 5030267119387.**<br>**5009044 - 5030267130863.**<br>**5009068 - 5030267152490.**<br>**5009190 - 5030267112562.**<br>**5010000 - 5030267068647.** |

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| | **5011000 - 5030267068661.**<br>**5011001S - 5030267077540.**<br>**5011005 - 5030267087082.**<br>**5012000 - 5030267068692.**<br>**5013005 - 5030267068753.**<br>**5013018 - 5030267068784.**<br>**5013019 - 5030267068807.**<br>**5015000 - 5030267068838.**<br>**5015004 - 5030267080168.**<br>**5018000 - 5030267068944.**<br>**5018000S - 5030267081585.**<br>**5018012 - 5030267145980.**<br>**5018013 - 5030267146543.**<br>**5020000 - 5030267069064.**<br>**5020000S - 5030267095469.**<br>**5020002 - 5030267093007.**<br>**5025000 - 5030267069101.**<br>**5025310 - 5030267069132.**<br>**5025310S - 5030267093175.**<br>**5026000 - 5030267069163.**<br>**5026310 - 5030267069170.**<br>**5080000 - 5030267069453.**<br>**5083008 - 5030267143122.**<br>**5113006 - 5030267069545.**<br>**5113010 - 5030267094516.**<br>**5113020 - 5030267069576.**<br>**5183000 - 5030267069750.**<br>**5183001 - 5030267069767.**<br>**5190009 - 5030267149629.**<br>**5191000 - 5030267069866.**<br>**5191004 - 5030267094363.**<br>**5191045 - 5030267150328.**<br>**5191160 - 5030267127603.**<br>**5191170 - 5030267096947.**<br>**5191172 - 5030267124510.**<br>**5191175 - 5030267119226.**<br>**5191176 - 5030267119189.**<br>**5191850 - 5030267069897.**<br>**5191852 - 5030267116379.**<br>**5191855 - 5030267119301.**<br>**5192000 - 5030267069903.**<br>**5194000 - 5030267069965.**<br>**5194006 - 5030267148837.**<br>**5194190 - 5030267112685.**<br>**5194850 - 5030267069972.**<br>**5196000 - 5030267128600.**<br>**5197000 - 5030267140947.**<br>**5197001 - 5030267156788.**<br>**5803000 - 5030267070473.**<br>**5804000 - 5030267070480.**<br>**5804011 - 5030267150755.**<br>**5804855 - 5030267119264.** |

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| | **5805000 - 5030267070534.**<br>**5805003 - 5030267118205.**<br>**5805006 - 5030267146727.**<br>**5805030 - 5030267156030.**<br>**5805031 - 5030267157839.**<br>**5805044 - 5030267070541.**<br>**5805175 - 5030267119240.**<br>**5808005 - 5030267094172.**<br>**5809130 - 5030267127412.**<br>**5809176 - 5030267124534.**<br>**5819002 - 5030267166411.**<br>**5825000 - 5030267124497.**<br>**RM21301 - 00619498213016.**<br>**RM21303 - 00619498213030.**<br>**RM21311 - 00619498213115.**<br>**RM21313 - 00619498213139.** |
| | **4. Primary clinical purpose of device(s)*** |
| | The Smoothbore Breathing Systems are intended to deliver and remove respiratory gases to and from a patient via a breathing system comprised of tubing and connectors. |
| 1. | **5. Device Model/Catalogue/part number(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.** |
| 1. | **6. Software version** |
| | N/A |
| 1. | **7. Affected lot numbers.** All lot numbers as listed below next to the device catalogue (product) reference number.<br><br>**5000000 -** 32521727; 32527291.<br>**5000012 -** 32504855; 32510565; 32513089; 32517505; 32523060; 32526688.<br>**5000019 -** 32507679; 32509753; 32514485; 32514542; 32520382; 32521349; 32523077; 32523770; 32526107; 32526689.<br>**5000022 -** 32505971; 32507363; 32511150; 32511259; 32512803; 32513453; 32517384; 32520672; 32521164; 32525556.<br>**5000034 -** 32504698; 32507785; 32509091; 32513454; 32516094; 32525501; 32527771. |

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| | **5000039 -** 32500600; 32502810; 32512576; 32516601; 32520881; 32520961; 32524212; 32524777.<br>**5000064 -** 32504798; 32505806; 32507713; 32512030; 32512398; 32521337; 32524506; 32525538; 32528403.<br>**5000190 -** 32516316.<br>**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.<br>**5001000S -** 32506950; 32511800; 32519577; 32522232.<br>**5003000 -** 32504783; 32508532; 32511294; 32517305; 32518210; 32526759.<br>**5004000 -** 32503003; 32503835; 32507030; 32509695; 32513371; 32514120; 32516924; 32518160; 32524203; 32525735.<br>**5005000 -** 32513732; 32525111; 32528487.<br>**5006000 -** 32501694; 32502924; 32505796; 32507485; 32507913; 32508639; 32509092; 32509512; 32510065; 32510492; 32511951; 32513683; 32513735; 32517225; 32519077; 32523868; 32526064; 32528108; 32529084.<br>**5007000 -** 32513279; 32517050; 32524844; 32527208.<br>**5007000S -** 32512207; 32517024; 32521313.<br>**5007001 -** 32500111; 32500424; 32505095; 32508712; 32511032; 32514557; 32517167; 32523957; 32524466; 32526601; 32528440.<br>**5007002 -** 32504020; 32507714; 32508292; 32512209; 32515259.<br>**5007003 -** 32517212; 32521555; 32526295; 32528642.<br>**5007004 -** 32504213; 32511344; 32524622; 32526444.<br>**5007005 -** 32504512; 32507839; 32517481; 32517586; 32527490; 32528806.<br>**5007006 -** 32500894; 32502402; 32505023; 32512031; 32513411; 32516096; 32523299; 32525808; 32528696.<br>**5007009 -** 32501199; 32508503; 32514919; 32517533; 32519823; 32521466; 32528798.<br>**5007010 -** 32501367; 32507332; 32510873; 32512490; 32512517; 32516748; 32519076; 32520407; 32523290.<br>**5007011 -** 32504995; 32507582; 32513547; 32515440; 32523298.<br>**5007012 -** 32500927; 32504480; 32509025; 32512624; 32517221; 32521570; 32525358; 32525738; 32528717.<br>**5008000 -** 32523637; 32526484.<br>**5008001 -** 32503308; 32507789; 32512530; 32515042; 32523121; 32523390; 32527008.<br>**5008002 -** 32506078; 32524747; 32527016.<br>**5008003 -** 32503377; 32504139; 32506502; 32510317; 32511878; 32514140; 32517600; 32521129; 32523189; 32523980; 32525610; 32525897; 32528211.<br>**5008006 -** 32502068; 32503170; 32504543; 32504915; 32507563; 32517770; 32518821; 32519881.<br>**5008019 -** 32503717; 32504607; 32509951; 32516967; 32520192; 32528223.<br>**5009000 -** 32500242; 32508640; 32512502; 32515974; 32512897; 32517347; 32516475; 32518199; 32519751; 32520944; 32521430; 32521675; 32523965; 32523699; 32525086; 32526043; 32527694; 32528202.<br>**5009000S -** 32513704; 32525441.<br>**5009001 -** 32504262; 32505917; 32510986; 32513288; 32514930; 32517822; 32520072; 32526905; 32527983.<br>**5009002 -** 32521024; 32525088. |

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|---|---|
| | **5009003 -** 32503173; 32504432; 32512708; 32513281; 32517476; 32517537; 32523787; 32526131; 32527313; 32528587.<br>**5009004 -** 32503247; 32506147; 32509402; 32515232; 32516648; 32518556; 32524582; 32525300; 32526921; 32527215.<br>**5009005 -** 32505983; 32508128; 32515141; 32515581; 32516602; 32518480; 32521147; 32524233; 32525271; 32526247; 32527107; 32528218.<br>**5009006 -** 32501624; 32502354; 32503847; 32504854; 32509033; 32511471; 32512677; 32514031; 32517224; 32517856; 32518982; 32521233; 32523936; 32524947; 32525976; 32527510.<br>**5009007 -** 32502737; 32503965; 32503967; 32504140; 32511070; 32512535; 32513347; 32513455; 32515575; 32516433; 32518378; 32519165; 32519414; 32520587; 32525704; 32526046; 32526720; 32527883; 32528110; 32528282; 32528610.<br>**5009009 -** 32505475; 32510613; 32514652; 32521609; 32525643; 32526486; 32528117.<br>**5009011 -** 32515347; 32522722; 32525319; 32527640.<br>**5009022 -** 32506833; 32512330; 32515963; 32517311; 32517756; 32519302; 32523534.<br>**5009033S -** 32512446; 32514869; 32518510; 32519153; 32519794; 32520567; 32521174; 32526944; 32528682; 32528886.<br>**5009034S -** 32511267; 32516185; 32519806.<br>**5009039 -** 32500748; 32506145; 32511004; 32515442; 32522423; 32523652; 32528224.<br>**5009044 -** 32502933; 32504831; 32507183; 32507905; 32511433; 32517457; 32519149; 32520360; 32523216.<br>**5009068 -** 32504876; 32506350; 32508645; 32517047; 32524002; 32528441.<br>**5009190 -** 32501405.<br>**5010000 -** 32505022; 32508126; 32511037; 32516366; 32518918; 32520160; 32527019.<br>**5011000 -** 32507922; 32512839; 32514048; 32516272; 32527761.<br>**5011001S -** 32503392; 32511860; 32512832; 32519064; 32520406; 32523844; 32524684; 32527753.<br>**5011005 -** 32503437; 32504940; 32509189; 32519284.<br>**5012000 -** 32503137; 32505082; 32507786; 32508504; 32509162; 32512225; 32513021; 32513651; 32515688; 32516906; 32519391; 32520411; 32525265.<br>**5013005 -** 32506647; 32508538.<br>**5013018 -** 32521568; 32527099.<br>**5013019 -** 32525346.<br>**5015000 -** 32508693; 32511469; 32512103; 32516168; 32516458; 32520504; 32521486; 32525791; 32526920; 32527425; 32528962.<br>**5015004 -** 32506683; 32509231; 32513050; 32513296; 32517159; 32521411; 32521500; 32525525; 32527865.<br>**5018000 -** 32511811.<br>**5018000S -** 32520615.<br>**5018012 -** 32512603; 32514141; 32520000; 32520480.<br>**5018013 -** 32515876; 32520947; 32524740; 32528882.<br>**5020000 -** 32503734; 32504313; 32507998; 32509521; 32510644; 32511025; 32513649; 32515659; 32518549; 32519670; 32522393; 32522653; 32522900; 32523218; 32523666; 32525478.<br>**5020000S -** 32505412; 32507729.<br>**5020002 -** 32503872; 32504142; 32511072; 32510996; 32521811; 32525060.<br>**5025000 -** 32510612; 32512388; 32515348; 32516407; 32522651.<br>**5025310 -** 32512902; 32515486; 32517832; 32525646; 32526115; 32527882.<br>**5025310S -** 32590070; 32590135; 32515668; 32517621; 32522650; 32525455; 32526938.<br>**5026000 -** 32525551.<br>**5026310 -** 32511510; 32525824. |

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|---|---|
| | **5080000 -** 32501226; 32504461; 32507010; 32509277; 32510197; 32513023; 32516196; 32517982; 32520647; 32520593; 32522345; 32524533.<br>**5083008 -** 32526488.<br>**5113006 -** 32501082; 32501516; 32506170; 32509213; 32521672; 32527637; 32527970.<br>**5113010 -** 32501518; 32505355; 32514071; 32519817.<br>**5113020 -** 32520573; 32522024.<br>**5183000 -** 32518070; 32527207.<br>**5183001 -** 32510200; 32519842.<br>**5190009 -** 32590067.<br>**5191000 -** 32511321; 32514264; 32515255; 32515350; 32516907; 32517823; 32520670; 32522190; 32522802; 32527182; 32528808.<br>**5191004 -** 32512810; 32512861; 32529033.<br>**5191045 -** 32512223; 32516909.<br>**5191160 -** 32516676.<br>**5191170 -** 32509625; 32512349; 32516486.<br>**5191172 -** 32506782; 32507341; 32508026; 32508369; 32508891; 32516574; 32516951; 32517058; 32519721.<br>**5191175 -** 32512869; 32515576; 32523665; 32524359; 32527509; 32528293.<br>**5191176 -** 32512414; 32517852; 32519093; 32522905; 32525267; 32526691; 32528520; 32528712; 32528939.<br>**5191850 -** 32521551; 32521655; 32526941.<br>**5191852 -** 32521572.<br>**5191855 -** 32505603; 32517962; 32518744; 32522429; 32524285; 32528095; 32528613.<br>**5192000 -** 32527864.<br>**5194000 -** 32512755; 32518705.<br>**5194006 -** 32521734; 32522776.<br>**5194190 -** 32502157; 32504794; 32507427; 32509088; 32512802; 32518832; 32522294.<br>**5194850 -** 32516377; 32518127.<br>**5196000 -** 32507474; 32507985; 32516014; 32525866; 32528460.<br>**5197000 -** 32504796; 32510202; 32512290; 32514056; 32520826; 32523170; 32524044; 32527212; 32527762.<br>**5197001 -** 32517434; 32523530; 32524226; 32526232; 32526264; 32527276.<br>**5803000 -** 32590217; 32512795.<br>**5804000 -** 32508034; 32509327; 32510695; 32510909; 32511535; 32511639; 32511812; 32513723; 32516032; 32516895; 32518659; 32519175; 32525543; 32525881; 32526271; 32527618; 32529063.<br>**5804011 -** 32505902; 32508874; 32515345; 32518483; 32518717; 32520468; 32520994; 32522700; 32524033; 32525553; 32525631; 32526731; 32527544.<br>**5804855 -** 32507336; 32508327; 32511169; 32515930; 32518257; 32521671; 32522570; 32523385; 32524372; 32525647; 32525826; 32527850; 32528547; 32528714.<br>**5805000 -** 32516315; 32517877.<br>**5805003 -** 32504185; 32505517; 32507074; 32508985; 32513592; 32514137; 32515353; 32515915; 32517075; 32519075; 32522810; 32523128; 32523515; 32524990; 32525786; 32527603; 32528318.<br>**5805006 -** 32504430; 32505025; 32506686; 32507902; 32510978; 32515968; 32516199; 32528636.<br>**5805030 -** 32505469; 32506841; 32513929; 32514276; 32515579; 32518484; 32519342; 32519468; 32519979; 32522143; 32522415; 32523651; 32525498; 32525628; 32526171; 32526270; 32527299; 32528409.<br>**5805031 -** 32528801. |

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|---|---|
| | **5805044 -** 32503990; 32508140; 32512372; 32514115; 32514515; 32515237; 32516030; 32516636; 32516710; 32517459; 32518657; 32519964; 32520413; 32525528; 32528049; 32528319; 32528713.<br>**5805175 -** 32526463; 32527372.<br>**5808005 -** 32502807.<br>**5809130 -** 32521009; 32525010; 32526719.<br>**5809176 -** 32507949; 32509058; 32509688; 32510125; 32510883; 32513045; 32514241; 32514825; 32516544; 32517306; 32519880; 32520250.<br>**5819002 -** 32590293; 32590402.<br>**5825000 -** 32521613.<br>**RM21301 -** 32500856; 32501850; 32518237; 32520934; 32522647; 32522944; 32528492.<br>**RM21303 -** 32504335; 32505604; 32506960; 32509777; 32510642; 32515194; 32519671; 32521465; 32521886; 32525806.<br>**RM21311 -** 32504259; 32504994; 32505686; 32506463; 32506964; 32507093; 32507589; 32508220; 32508453; 32508709; 32509182; 32509690; 32510110; 32510332; 32510825; 32511221; 32511692; 32511888; 32512183; 32512498; 32512838; 32513291; 32514044; 32514272; 32514431; 32514648; 32515106; 32514782; 32515233; 32515778; 32516268; 32516414; 32516639; 32517051; 32517486; 32517854; 32518054; 32518138; 32518488; 32518923; 32519009; 32519533; 32521197; 32521533; 32522344; 32523153; 32524732; 32525702; 32526787; 32526900; 32527298; 32527542; 32528119; 32529051.<br>**RM21313 -** 32502957; 32505658; 32508069; 32509040; 32511470; 32511646; 32511929; 32513375; 32514750; 32515341; 32516170; 32518029; 32518743; 32521826; 32523115; 32525363; 32525693; 32528085. |
| 1. | **8. Associated devices** |
| | N/A. |

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| | **2. Reason for Field Safety Corrective Action (FSCA)*** |
| 2. | **1. Description of the product problem*** |
| | During the manufacture of these products, Tetrahydrofuran (THF) solvent is used to bond the soft connectors onto the Smoothbore tube. Following reports received from the market of disconnection of the soft connectors from the tube, our investigation and testing of internal stock has identified insufficient amount of solvent used to ensure a secure connection. |
| 2. | **2. Hazard giving rise to the FSCA*** |
| | Disconnection of the connector from the smoothbore tube would result in a loss of ventilation, compromised or stopped ventilation, which may cause the patient to desaturate until ventilation is manually re-initiated.<br>Depending on the individual patient, the specific situation and time to re-initiate ventilation, loss of ventilation could potentially lead to organ failure, brain damage or death caused by hypoxia. |
| 2. | **3. Probability of problem arising** |
| | Our investigation and evaluation of all available information has estimated the probability of failure rate to be remote and potentially affecting 1 in 100 000 to 1 in 1 000 000 products. |
| 2. | **4. Predicted risk to patient/users** |
| | The risks associated with the identified faults have been evaluated and the predicted risk to patient has been assessed as high. Whilst the probability of occurrence is remote, we believe it is essential to address the issue promptly to further reduce the risk of any potential patient harm. |
| 2. | **5. Further information to help characterise the problem** |
| | N/A |
| 2. | 6. Background on Issue |
| | Following customer reports from the market and subsequent investigation and thorough inspection as well as testing of internal stock, we have identified that some products have been manufactured with insufficient amount of Tetrahydrofuran solvent. This unfortunately means that some of the connectors used in these devices might disconnect during use due to insufficient amount of solvent used during the manufacturing process. |
| 2. | 7. Other information relevant to FSCA<br><br>N/A |
| | **3. Type of Action to mitigate the risk*** |

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| **3.** | **1. Action To Be Taken by the User***<br><br>☒ Identify Device ☒ Quarantine Device ☒ Return Device **or** ☒ Destroy Device<br><br>☐ On-site device modification/inspection<br><br>☐ Follow patient management recommendations<br><br>☐ Take note of amendment/reinforcement of Instructions For Use (IFU)<br><br>☒ Other ☐ None<br><br>Please distribute this Field Safety Notice to all potential users of the Spirometry Sets and Anaesthetic Breathing Systems containing Spirometry Sets as listed above, within your facility for their awareness of the potential problem and to carry out the following actions:<br><br>1. Please identify and immediately quarantine any potentially affected products from the affected codes and lot numbers listed above.<br>2. Please complete the Reply Form below to confirm the potentially affected products you have identified and quarantined, so we can arrange a credit or replacement.<br>3. Please confirm in the Reply Form if you have destroyed the stock, or if you require the stock to be collected.<br>4. If you have no affected devices in stock, please also confirm this using the Reply Form below.<br>5. Please return the Reply Form provided below to giedriusb@intersurgical.lt or you local distributor, to confirm receipt of this notice and that the necessary actions have been taken.<br><br>**Please note**: This is a product removal (Recall)<br><br>Please continue to report to Intersurgical any adverse events involving these products. | |
| 3. | 2. By when should the action be completed? | Immediately on receipt of this FSN, and awareness of this FSN should be ongoing until all potentially affected stock listed in this FSN has been used up or replaced. |
| 3. | 3. Particular considerations for: N/A<br><br>Is follow-up of patients or review of patients' previous results recommended?<br><br>Not applicable. | |
| 3. | 4. Is customer Reply Required? *<br>(If yes, form attached specifying deadline for return) | Yes |
| **3.** | **5. Action Being Taken by the Manufacturer**<br><br>☒ Product Removal ☐ On-site device modification/inspection<br>☐ Software upgrade ☐ IFU or labelling change<br>☒ Other ☐ None<br><br>Corrective actions have been implemented in the manufacturing process to eliminate this problem for ongoing supply. Intersurgical will replace all affected products free of charge. Please contact Intersurgical or your direct supplier for credit or replacement. | |

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| 3 | 6. By when should the action be completed? | As soon as possible from receipt of the FSN but no later than 31/12/2026. |
| 3. | 7. Is the FSN required to be communicated to the patient /lay user? | No |
| 3 | 8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? | |
| | N/A | |

| | | |
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| | **4. General Information*** | |
| 4. | 1. FSN Type* | New – Recall Notice |
| 4. | 2. For updated FSN, reference number and date of previous FSN | N/A |
| 4. | 3. For Updated FSN, key new information as follows: | |
| | N/A | |
| 4. | 4. Further advice or information already expected in follow-up FSN? * | No |
| 4 | 5. If follow-up FSN expected, what is the further advice expected to relate to: | |
| | N/A | |
| 4 | 6. Anticipated timescale for follow-up FSN | N/A |
| 4. | 7. Manufacturer information<br>(For contact details of local representative refer to page 1 of this FSN) | |
| | a. Company Name | **Intersurgical Ltd.** |
| | b. Address | **Crane House, Molly Millars Lane, Wokingham, Berkshire, RG41 2RZ** |
| | c. Website address | **https://www.intersurgical.com/** |
| 4. | 8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * | |
| 4. | 9. List of attachments/appendices: | **Customer Reply Form** |
| 4. | 10. Name/Signature | **Ivan Seniut, Group Quality and Regulatory Affairs Director, Intersurgical** |
| | |   |

# FSCA Ref: 632673

| | Transmission of this Field Safety Notice |
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| | This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)<br><br>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)<br><br>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.<br><br>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback. |

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.