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Clinical Publications & Summary Statements

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Urology

Summary Statements:

1. In 9 Urology studies, over 2,000 patients experienced a shorter procedure time due to AirSeal®'s ability to maintain a stable, clear working spaceat a lower intra-abdominal pressure, even with continuous suction or large leaks. 22, 23, 24, 25, 27, 29, 32, 35, 38

2. AirSeal® has reduced the cost of care for over 4,000 patients across 17 Urology studies. Our unique technology allows surgeons to safely operateat lower intra-abdominal pressures which improves procedural efficiency, reduces post-operative pain, and leads to a shorter hospital stay whencompared to conventional insufflation. 4, 6, 7, 13, 15, 18, 20, 22, 23, 24, 25, 26, 27, 29, 32, 35, 38

3. Almost 2,000 patients across 5 Urology studies experienced a shorter length of stay when surgeons utilized AirSeal® at an intra-abdominal pressure lower than 15mmHg. 15, 22, 23, 24, 35

Author	Journal	Publication Type	Focus of Study	Study Design	# of Subjects	Key Metrics	Key Findings
Abaza	Journal of Urology	Consecutive, Retrospective	Robotic Prostatectomy	Factors Associated with Same Day Discharge (AirSeal® at 6mmHg)	500 Patients	Day of Discharge	1. Patient charges were significantly lower for patientsthat were discharged on the day of surgery with noincrease in readmissions or emergency visits
Abaza, Ferroni	Journal of Urology	Randomized, Double-blinded, Controlled Trial	Robotic Prostatectomy	AirSeal® at 6mmHg vs. AirSeal® at 15mmHg	138 Patients (67 at 6mmHg, 71 at 15mmHg)	Pain Scores, Ventilatory Metrics	The 6mmHg group showed: 1. Significantly lower post-op pain scores 2. Improved ventilation - reduced etCO2 & PIP, reducedMAP

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Abaza, Ferroni	British Journal of Urology International	Prospective, Consecutive	Robotic Prostatectomy	AirSeal® at 6mmHg vs. AirSeal® at 15mmHg	600 Patients (300 AirSeal® at 6mmHg, 300 AirSeal® at 15mmHg)	Procedure Time, EBL, Post-op Pain, LOS, Complications, 30-day Readmission	The 6mmHg group showed: 1. Patients had lower max pain scores between 5 and 12 hours 2. Fewer overall complications 3. The mean LOS was shorter (0.57 vs 1 day) 4. 43.3% of patients were discharged on the day of surgery 5. Fewer patients returned to the ER within 30 days 6. Fewer patients were readmitted within 30 days
Annino	Surgical Endoscopy	Prospective, Consecutive	Robotic Partial Nephrectomy	AirSeal® vs. SI at 12-15mmHg	122 Patients 67 AirSeal® at 12-15mmHg, 55 SI at 12-15mmHg)	Procedure Time, Warm Ischemia Time	The AirSeal® group showed: 1. Procedures were 10.8% shorter in duration 2. Warm ischemia time was 38.9% shorter 3. A significant increase in the number of cases performed as "zero ischemia" (clampless) was observed in the AirSeal® group (20 vs 4 cases)
Covotta	Anesthesia & Analgesia	Prospective, Parallel	Robotic Cystectomy	AirSeal® vs. SI at 10-14mmHg	56 Patients (28 AirSeal® at 12mmHg, 28 SI at 12mmHg)	Ventilation, Hemodynamic Metrics	Patients in the AirSeal® group showed: 1. Lower inspiratory plateau pressure (Pplat) 2. Lower minute volume (MV) 3. Lower etCO2 4. Significantly higher static compliance (Cstat)
Desroches	Urology (The Gold Journal)	Prospective, Randomized, Multi-center	Robotic Partial Nephrectomy	AirSeal® at 12mmHg vs. AirSeal® at 15mmHg vs. SI at 15mmHg	202 Patients (66 AirSeal® at 12mmHg, 69 AirSeal® at 15mmHg, 66 SI at 15mmHg)	Insufflation-related Complications, Ventilation Metrics, LOS	1. Patients in the 12mmHg AirSeal® group developed subcutaneous emphysema less often than patients in both the AirSeal® 15mmHg and SI 15mmHg groups 2. Peak airway pressure was lower in both AirSeal® groups vs. the SI group 3. etCO2 was lower in the AirSeal® 12mmHg group vs. both the AirSeal® 15mmHg and SI 15mmHg groups

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El-Hajj, Ayoub	World Journal of Urology	Single-tertiary Center Study	Robotic Prostatectomy	AirSeal® at 10mmHg vs. SI at 12mmHg	326 Patients (125 AirSeal®, 201 SI)	Perioperative Outcomes, Post-op Complications	AirSeal® was associated with: 1. Shorter operative times by 12.3 minutes 2. Shorter length of hospital stay by 0.5 days 3. Lower odds of Clavien-Dindo complications
Fan	Journal of Robotic Surgery	Systematic, Meta-analysis	Robotic Partial Nephrectomy	AirSeal® vs. SI	379 Patients (194 AirSeal®, 185 SI)	SCE, Post-op Pain Scores	AirSeal® group showed: 1. Significantly lower rates of subcutaneous emphysema 2. 12hr post-operative pain scores significantly lower
Feng, Porter	Journal of Urology	Prospective Randomized Controlled Trial	Partial Nephrectomy	AirSeal® at 12mmHg, AirSeal® at 15mmHg, and SI at 15mmHg	93 Patients (31 AirSeal® at 12mmHg, 31 AirSeal® at 15mmHg, 31 SI at 15mmHg)	SCE, Pain, LOS, Recovery Time	1. AirSeal® insufflation at 12mmHg was associated with areduced risk of developing subcutaneous emphysema 2. Pain was decreased in both AirSeal® groups comparedto standard insufflation
Forte, Sorrenti	Frontiers in Surgery	Retrospective	Lap Partial Nephrectomy	AirSeal® vs. SI at 12mmHg	27 Patients (14 AirSeal® vs. 13 SI)	Mean Operative Time, Blood Loss, Ischemia Time, Complications (SCE, PT, PM)	AirSeal® group showed: 1. Lower operative time (107.5 min in AirSeal® group vs.120 min in SI group) 2. Lower complication rates 3. Decreased perioperative blood loss (1.45g/dL vs2.2g/dL) 4. Reduced warm ischemia time (18 min vs. 20 min)
Kavoussi, Wimhofer	World Journal of Urology	Single-site, Retrospective	Robotic Prostatectomy	AirSeal® at 10mmHg vs. SI at 12mmHg	642 Patients (257 AirSeal®, 385 SI)	Procedure Time	1. Mean operative time decreased by 23.2 min inAirSeal® group vs. SI group

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Landman	Urology (The Gold Journal)	Prospective, Randomized	Laparoscopic Renal & Peri-Renal Surgery	AirSeal® at 15mmHg vs. SI at 15mmHg	56 Patients (28 AirSeal® at 12mmHg, 28 SI at 12mmHg)	Pressure Variability, Physiological Effects	Patients in the AirSeal® group: 1. Had a pneumoperitoneum that was far more stable or less variable than patients in the Standard Insufflation group 2. Had a lower etC02 after 10 minutes of insufflation than patients in the SI group
Lee	Society of Laparoscopic and Robotic Surgeons	Consecutive, Prospective	Robotic Prostatectomy	AirSeal® at 15mmHg vs. SI at 15mmHg	200 Patients (100 AirSeal® at 15mmHg, 100 SI at 15mmHg)	Procedure Time, Post-op Pain, N/V, LOS, Complication Rate	1. Procedures in the AirSeal® group were 12.6% shorter in duration 2. Patients in AirSeal® group had fewer episodes of nausea (2% vs 10%) 3. Trend towards less pain in the AirSeal® group within the first 24 hours after surgery
Lu, Zou	International Journal of Surgery	Meta-analysis	Minimally Invasive Urological Surgery	AirSeal® (VIS) vs. Standard (CIS) at Various Pressures	13 Studies, 1875 Patients (836 VIS, 1039 CIS)	Peri-operative Outcomes	AirSeal® resulted in: 1. Significantly lower Clavien-Dindo III-IV complications 2. Significantly reduced general and shoulder pain at 12-24h post-op 3. Reduced LOS
Mottrie, Vandenbr-oucke	Clinical Genitourinary Cancer	Prospective, Single Center	Robot-assisted Radical Prostatectomy (RARP)	AirSeal® at 8mmHg	53 Patients at 8mmHg	Central Venous Pressure (CVP), Mean Airway Pressure	1. Central venous pressure and mean airway pressure showed improvements when AirSeal® was used
Badani	Journal of Laparo-endoscopic & Advanced Surgical Techniques	Meta-analysis	Robotic Urologic Surgery	AirSeal® vs. SI at Various Pressures	10 Studies, 1,765 Patients	PAP, Minute Volume, etCO2, Static Compliance, Complication Rates, Operating Time	The AirSeal® group showed: 1. Lower inspiratory plateau pressure, lower minute volume, lower ETCO2, lower C02 elimination rate, higher static compliance 2. Improved cardiopulmonary parameters 3. Some studies showed decreased complication rates at low pressure

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Rohloff, Maatman	Journal of Robotic Surgery	Prospective, Randomized, Double-blinded Trial	Robotic Prostatectomy	AirSeal® at 12mmHg vs. AirSeal® at 15mmHg	407 Patients (198 AirSeal® at 12mmHg, 209 AirSeal® at 15mmHg)	LOS, Post-op Ileus	Patients in the AirSeal® at 12mmHg group: 1. Had a significantly shorter LOS 2. Showed lower occurrence of post-operative ileus (decreased from 12% to 5%)
Xu	World Journal of Urology	Randomized Controlled Trial	Robotic Partial Nephrectomy	AirSeal® at 12mmHg vs. SI at 15mmHg	62 Patients (31 AirSeal®, 31 SI)	Rate of Subcutaneous Emphysema (SCE)	AirSeal® group showed: 1. Significantly lower subcutaneous emphysema rate than the conventional group 2. Significantly lower etCO2, PaCO2 at the end of the operation, lower tidal volumes and frequency of scope cleaning 3. Significantly lower post-op pain scores at 8hr, 12hr and at time of discharge
Yezdani	The Journal of Urology	Single-site, Perspective	Robotic Prostatectomy	AirSeal® vs. 12mm Standard Versaport	149 Patients (70 with AirSeal®, 79 with SI)	Operative Time, EBL, LOS, Pain Scores	AirSeal® group showed: 1. Significantly less operative time (146min vs. 167min) 2. Reduction in intraoperative blood loss (132ml vs. 215ml) 3. Pain scores at 6-12 hours post-op were significantly lower (3.3 vs. 4.1) than the SI group
Zhi, Wang	Journal of Robotic Surgery	Meta-analysis	Robot-assisted Radical Prostatectomy	AirSeal® vs. SI at Various Pressures	1503 Patients (657 AirSeal®, 846 SI)	Peri-operative Outcomes	1. AirSeal® results in shorter operative time, reduced hospital stays and fewer major complications

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Vasdev	BJUI	Prospective, Consecutive	Robot-assisted Radical Cystectomy	AirSeal® at 15mmHg vs. AirSeal® at 12mmHg	20 Patients (10 AirSeal® at 15mmHg, 10 AirSeal® at 12mmHg)	Flatus/Stools, Ileus Rates	The 12mmHg AirSeal® group: 1. Had a 40 min shorter operative time and 1-day shorter LOS than the 15mmHg group 2. Had fewer patients with ileus (10% vs. 30%) compared to the 15mmHg group 3. Passed flatus 1 day earlier and stooled 1.5 days earlier than 15mmHg group 4. The study found that patients in the 15mmHg AirSeal® group had a higher risk of paralytic ileus post robotic cystectomy and robotic intracorporeal urinary diversion
Siddiqui	Journal of Robotic Surgery	Systematic Review, Meta-analysis	Partial Nephrectomy	AirSeal® at 12mmHg vs. Standard at 15mmHg	5 Studies, 427 Patients (220 AirSeal®, 207 Standard)	etCO2	1. AirSeal® significantly lowers etCO2 in patients undergoing LPN, which can therefore impact recovery and complication rates

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