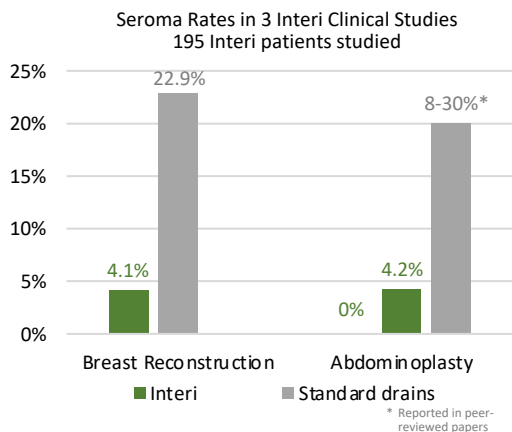


## CLINICAL DATA OVERVIEW

Clinical experience with the Interi® System (IC Surgical, Grand Rapids, MI) has been reported in three studies published in peer reviewed journals: a retrospective two-arm study in breast reconstruction,<sup>1</sup> a prospective pilot study in abdominoplasty,<sup>2</sup> and a retrospective case series in abdominoplasty.<sup>3</sup>

Figure 1



Seroma is the most common reported complication following abdominoplasty and breast reconstruction. Seroma results in patient distress, increased office visits, undesirable aesthetic outcomes, and higher risk of infection and prosthesis loss in breast reconstruction. Factors responsible for its genesis are multiple, including large, undermined skin flaps producing dead space and shear forces creating continuous micromotion at the interface of the adipose tissue layer in abdominoplasty, and large dead space created by the mastectomy, insertion of a foreign body, movement of the chest wall and lymphatic disruption in breast reconstruction.<sup>2,4</sup>

Seroma rates were assessed in all three Interi studies, and these results are summarized and compared to seroma rates in patients utilizing standard post-surgical drains (Figure 1).

### Reduction in Seroma and Other Complications with a Novel Internal Negative Pressure System in Breast Reconstruction

Robert Paul, MD; *Plastic and Reconstructive Surgery Global Open*, Volume 11, Issue 1, September 2023

Retrospective study of the Interi System in prepectoral breast reconstruction demonstrated a significant reduction in complications compared to standard drains. Data from 100 consecutive Interi patients and 100 standard drain patients was compared. All breast surgical procedures were performed by a single breast surgeon, and all breast reconstructive procedures were performed by a single reconstructive plastic surgeon. Both groups were well matched in all demographic, reconstructive, and mastectomy variables. Significant differences were reported in seroma, skin/mastectomy flap revision, any complication, and duration of therapy. (Figure 2). Subgroup analysis of obese patients showed a similar significant reduction in these complications. The reductions in seroma and flap revision are indicative of improved internal wound healing across a broad spectrum of patients.

Figure 2

	Interi n=170 breasts	Standard drains n=166 breasts	P
Seroma	7 (4.1%)	38 (22.9%)	<0.00001
Skin/flap revision	18 (10.6%)	36 (21.7%)	0.006
Any complication	40 (23.5%)	73 (44.0%)	0.0001
Duration of therapy	16.5 days ± 3.5	19.6 days ± 6.2	<0.0001
Age, mean	49.8 ± 12.6	51.7 ± 12.2	0.124
BMI kg/m <sup>2</sup>	28.1 ± 5.9	28.6 ± 6.2	0.560
Direct to implant	73 (42.9%)	93 (56.0%)	0.016
Tissue exp./implant	97 (57.1%)	73 (44.0%)	0.016

### The Internal Negative-Pressure Wound Control System: A Paradigm Shift for Promoting Deep Space Healing in Complex Surgically Created Wounds

Kenneth C. Shestak, MD; *Aesthetic Surgery Journal*, Volume 41, Issue 11, November 2021

This paper reports on the use of a novel technology in a prospective cohort of 24 consecutive patients undergoing full abdominoplasty. The internal wound closure system provides continuously generated negative pressure (-125 mmHg) throughout the surgically created space by means of a multibranching manifold. All patients underwent placement of the internal device concurrent with abdominoplasty procedure. Patients were seen on POD 1, 3, 7 and 30 for wound and pain assessment. Results at 30 days revealed no clinical seroma, and no evidence of wound-healing issues (Figure 3). All patients and surgeons expressed high satisfaction with the performance and function of the device.

Figure 3

Interi System prototype	n=24 patients
Seroma	0%
Patient and surgeon reported satisfaction	4.8 (on 5-point scale)
Manifold removal	100% at POD 7
Mean fluid output	551 mL (range, 240-2205 mL)

## CLINICAL DATA OVERVIEW, CONTINUED

### Defining Internal Tissue Closure: High-Resolution Ultrasound Evaluation of Interi— A Novel Internal Tissue Closure System

David Alfonso, MD, FACS; Bradley Bengtson, MD, FACS; and Patricia McGuire, MD, FACS; *Aesthetic Surgery Journal Open Forum*, Volume 4, September 2022

This retrospective case series reports experience with Interi in 71 consecutive full abdominoplasty patients. High-resolution ultrasound (HRUS) was used to evaluate Interi’s ability to evacuate blood and fluid, hold internal tissues together and document, for the first time, what internal tissue healing actually looks like radiographically. HRUS was performed routinely either on the day of manifold removal or subsequent visits. Recorded HRUS images were evaluated by an independent radiologist with no fluid identified except in 3 (4.2%) patients in whom surgeons had also noted fluid collections (Figure 4). HRUS allowed for visualization of the plane of tissue healing and accurately defines what internal tissue closure looks like radiographically (Figure 5). The authors observed that the overlying abdominal skin flaps have visibly reduced edema and were much softer and more pliable in patients who received Interi.

Figure 4

Interi System	n=71 patients
Seroma fluid visible on high-resolution ultrasound (HRUS)	3 (4.2%)
Long-term >30-day seroma following treatment	0%
Manifold removal, mean, range	9.1 days (5-18)
Mean fluid output, mean, range	570 mL (90-1550 mL)
Age, mean, range	42.3 (21-74)
BMI kg/m <sup>2</sup> , mean, range	27.6 (19-44)

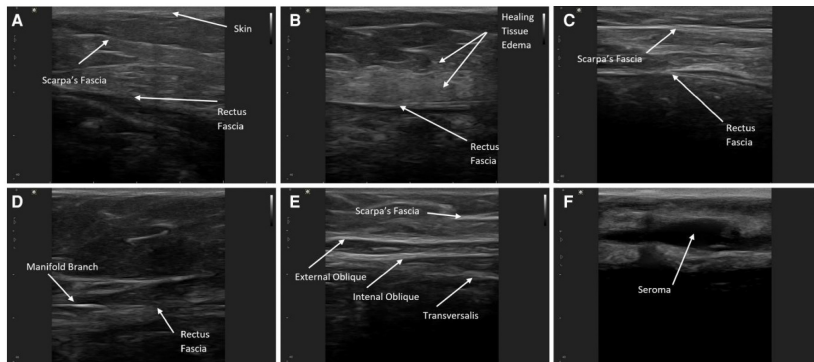


Figure 5

(A-E) Sample HRUS images from consecutive Interi patients undergoing full abdominoplasty. Images recorded at the time of device removal easily identify any fluid present, healing tissue planes, Scarpa’s fascia, abdominal fascia, manifold branches, and most importantly the approximated deep tissue plane, where the overlying skin flap junction is healing to the abdominal fascia. (F) Image from one of the 3 postoperative patients that developed a seroma.

## PRE-CLINICAL DATA

Development of the Interi System involved an iterative series of pre-clinical studies to demonstrate effectiveness of the platform concept and design the proprietary branching manifold. A series of 12 animal studies were implemented to demonstrate system effectiveness, including 77 total subjects. Figure 6a and 6b are representative gross observations of explanted tissue from one of the comparison studies in a porcine model. Gross observations showed better tissue healing for IC Surgical manifold group vs. standard of care.

#### Key findings related to manifold

Demonstrated biocompatibility

Confirmed material strength

No infiltration of tissue

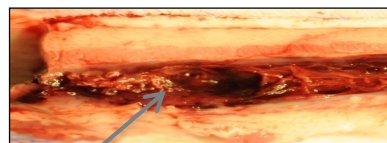
Removal force same as standard of care

#### Key findings related to overall system

Showed effectiveness of the therapy

Achieved fluid removal expectations

Figures 6a and 6b



Visual assessment of explanted tissue treated with standard of care demonstrates poor healing with gaps for fluid accumulation and weakened repair.



Visual assessment of explanted tissue treated with IC Surgical technology demonstrates closed tissue planes and evidence of healing.

**References:** 1. Paul, Robert MD. Reduction in Seroma and Other Complications with a Novel Internal Negative Pressure System in Breast Reconstruction. *Plastic & Reconstructive Surgery-Global Open* 11(9):p e5261, Sept 2023. 2. Shestak KC. The Internal Negative-Pressure Wound Control System: A Paradigm Shift for Promoting Deep Space Healing in Complex Surgically Created Wounds. *Aesthet Surg J*. 2021 Oct 15;41(11):NP1543-NP1549. 3. Alfonso D, Bengtson B, McGuire P. Defining Internal Tissue Closure: High-Resolution Ultrasound Evaluation of Interi-A Novel Internal Tissue Closure System. *Aesthet Surg J Open Forum*. 2022 Sep 20; 4:ojac073. 4. Jordan SW, Khavanin N, Kim JYS. Seroma in Prosthetic Breast Reconstruction. *Plast Reconstr Surg*. 2016 Apr;137(4):1104-1116.