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Breast

# A Novel Internal Negative Pressure Delivery System in Prepectoral Breast Reconstruction—Preliminary Experience

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**Background:** Seroma remains a common complication after breast surgery, despite meticulous surgical technique to obliterate dead space and use of standard post-surgical drains for fluid evacuation. Therefore, novel approaches are needed. The Interi System is an internal, negative-pressure delivery system consisting of a manifold that is a silicone tubing with a central trunk and three peel-apart channeled branches connected to an external therapy unit, which simultaneously delivers continuous negative pressure of 125 mm Hg and removes excess fluid from internal tissue planes. This retrospective study evaluated the safety and effectiveness of Interi compared with standard drains in consecutive patients undergoing immediate, prepectoral, acellular dermal matrix-assisted, and implant-based breast reconstruction.

**Methods:** Patient records were reviewed, and data on demographics, mastectomy, and reconstructive variables, postoperative complications, fluid output volume, and manifold/drain duration were retrieved and compared between the two groups.

**Results:** Interi was used in 23 patients (38 breasts) and standard drains in 23 patients (39 breasts). Patients in both groups were well matched in all demographic, reconstructive, and mastectomy variables. Interi duration was significantly shorter than drains (16.7 versus 19.7 days; $P = 0.020$). There were no instances of seroma formation after removal of the manifold, edematous flap, or reconstructive failure with Interi. Seroma rate was 20.5% after drain removal ($P = 0.005$). All other complications were similar between the two groups.

**Conclusion:** Interi effectively removed excess fluid from internal tissue compartments in prepectoral breast reconstruction and may offer significant improvement over current standards of care for seroma prevention in this procedure.
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## INTRODUCTION

Seroma, a collection of serous fluid containing blood plasma and/or lymph fluid, is a common adverse effect after breast surgery.[1] It is most prevalent after mastectomy and axillary lymph node dissection, accumulating in the dead space beneath the skin flaps or in the axillary space, respectively. Reported incidences vary widely, ranging from 15% to over 90%, depending on various risk factors, including body mass index, diabetes, extent and duration of breast surgery, drainage system used, and dissection instrument used.[2–4] The use of acellular dermal matrices in implant-based breast reconstructions, a current trend,[5] may additionally contribute to seroma formation.[6] Although seroma is not life threatening, it can lead to significant morbidity, including delayed wound healing, risk of infection from repeated seroma aspirations, prolonged hospital stays, skin flap necrosis and subsequent implant loss, patient discomfort, repeated visits to the outpatient clinic, delay in commencing adjuvant therapies, and additional healthcare costs.[1,7]

Several approaches have been or are used to prevent or mitigate seroma formation, including surgical techniques [tissue dissection techniques, techniques to reduce or obliterate dead space (quilting, flap fixation)], the use of sealants (fibrin glue) and sclerotherapy, compression dressing, the use of closed-suction surgical drains (standard drains), shoulder exercise, and the use

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of octreotide.[8] None of these approaches individually has been shown to be consistently and reliably effective. Currently, the most commonly used approach is a combination of surgical techniques to obliterate dead space and the use of standard drains (Jackson Pratt). However, despite their widespread use, these common approaches have not demonstrated consistent success in closing internal tissue planes in the reconstructed breast and eliminating seromas, as evidenced by the high rate of seroma in published studies.[2–4] Novel approaches are, thus, needed to address this clinical problem.

One such approach is the Interi System (IC Surgical, Grand Rapids, Mich.), an internal negative pressure delivery system (Fig. 1). Interi encompasses an internal manifold, which is an extruded silicone tube with a central trunk along with three "peel-apart" channel branches, connected to an external therapy unit that simultaneously delivers continuous negative pressure of 125 mm Hg to tissue planes and removes excess fluid from subcutaneous spaces, producing immediate and sustained apposition of tissues in this interface (Fig. 2). Based on this mechanism of action, it is expected that Interi has the potential to more effectively close down internal tissue planes, resulting in reduced seroma, swelling, and other complications.

This retrospective study reports on the use of Interi in patients undergoing immediate, prepectoral, implant-based, breast reconstruction. The study evaluated the safety and effectiveness of Interi by comparing the incidence of seroma formation after therapy discontinuation and other postoperative complications in patients who received Interi with patients who received standard drains.

## Takeaways

**Question:** Seroma remains a common complication after breast surgery, despite numerous approaches to close dead space and remove fluid.

**Findings:** Interi System is a novel internal negative pressure delivery system to close internal tissue planes and remove excess fluid. This study evaluated seroma and other post-operative complications in Interi versus standard drains in prepectoral breast reconstruction. Patients using Interi had no seroma after Interi removal. Overall complications, seroma, and duration of therapy were significantly lower in the Interi patients.

**Meaning:** Interi offers an effective means to remove fluid and close internal tissue planes and may help reduce seroma formation in breast reconstruction patients.

## PATIENTS AND METHODS

### Study Criteria

This is a retrospective study of consecutive patients who underwent immediate implant-based prepectoral breast reconstruction from September 2020 to April 2021 in the author's practice. Patients who underwent direct-to-implant or two-staged tissue expander/implant reconstruction were included, but those who underwent delayed reconstruction, hybrid procedures (implant and latissimus flap), or revision reconstruction were excluded. Patients were stratified into two groups: those who received Interi for internal wound closure and fluid management, and those who received standard drains. The study was approved by St. Vincent Health Institutional Review Board (Indianapolis, Ind.).

### Reconstructive Details

All breast surgical procedures were performed by a single breast surgeon, and all breast reconstructive procedures were performed by a single reconstructive surgeon (RP). Prepectoral breast reconstruction was performed according to the reconstructive surgeon's routine standard of care. Following mastectomy, the prepectoral space was prepared for implant or tissue expander placement, paying particular attention to dead space management. Acellular dermal matrix was used in all reconstructions to provide prosthesis coverage and support. The same types of acellular dermal matrix, expander, and implant were used across all reconstructions.

After the introduction of the prosthesis and acellular dermal matrix, two types of fluid management systems were utilized: Interi or standard drains. When using Interi, three branches of the internal manifold were


**Fig. 1.** The Interi System.

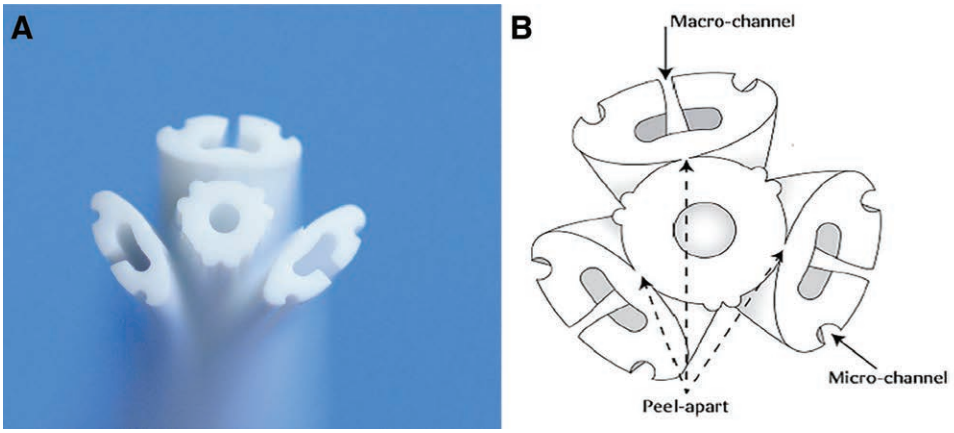


**Fig. 2.** The manifold tip. A, Close-up view of manifold tip with branches partially peeled. B, Engineering schematic with micro-channels identified.

placed in the subcutaneous plane (one centered over the prosthesis, one at the superior border, and one at the inferior border) and the fourth was placed in the peri-implant space behind the prosthesis and ADM to achieve maximal coverage of internal tissue planes (Fig. 3). Using a trocar, the manifold tubing was tunneled down inferiorly through the chest wall and exited through a single opening at the inferior lateral portion of the breast below the extent of the mastectomy incision. Following incision closure, dressings were applied over the manifold exit site and incision closure, per standard practice. These included a protective disc dressing (GuardIVa CHG/Hemostatic, BD, Franklin Lakes, N.J.) over the manifold exit site and a transparent film dressing (Tegaderm, 3M Health Care, St. Paul, Minn.) over the incision and manifold exit sites, which were typically retained until the manifold was removed postoperatively. After the dressings were in place, the exited manifold was attached to a therapy unit via a connector (Fig. 4). The therapy unit is a single-use, wearable device that supplies negative pressure and collects the evacuated fluid. When the therapy unit is full, it is detached by the patient and replaced with a new one. At discharge, patients were provided with replacement therapy units and taught to read fluid levels in the therapy units and to change full therapy units for new ones.

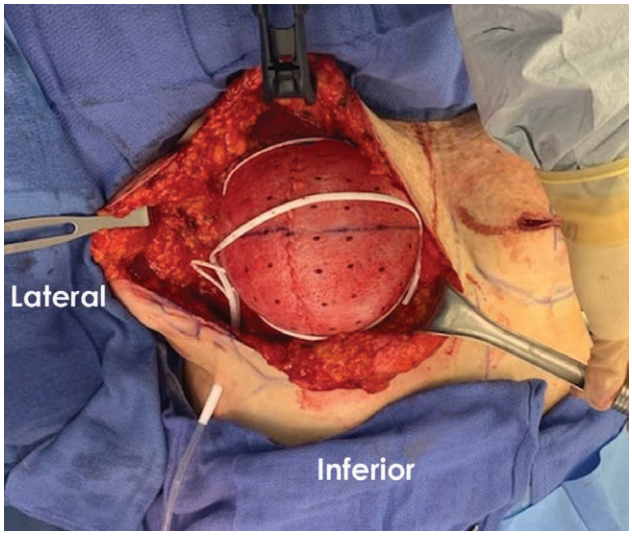


**Fig. 3.** Placement of manifold branches intraoperatively. Three of the manifold branches are placed in the subcutaneous space (as shown), with the fourth branch placed under the prosthesis in the peri-implant space (hidden from view). The manifold is exited through a single opening (as shown) and connected to a therapy unit (not shown).


**Fig. 4.** Manifold attached to therapy unit.

When using standard drains, one drain was placed along the entire inferior aspect of the breast pocket, and the tubing was tunneled to a single lateral exit site per usual protocol. At discharge, patients were taught to measure fluid in suction bulbs, empty and dispose of fluid from the bulbs, and prime the bulbs to reinitiate suction. After incision closure, dressings were applied over the drain exit site and incision closure, per standard practice, as described above for Interi.

### Patient Follow-up

Postoperatively, patients were followed in the office per standard protocols that included scheduled visits at postoperative days 7–9, at postoperative days 14–21, and 7 days after manifold/standard drain removal. At each visit, patients were assessed for any postoperative complications, including complications at wound sites (manifold/standard drain tubing exit site and mastectomy incision site). Manifolds/standard drains were removed when output volumes were 30 $cm^3$ or less for at least 3 days.

### Data Collection and Analyses

Patients who met the inclusion criteria were stratified by the type of fluid management system utilized (ie, Interi or standard drains). Patient records were reviewed, and data on demographics, comorbidities, neoadjuvant therapy use, type of mastectomy, mastectomy specimen weight, type of reconstruction, postoperative complications (including seroma), volume of fluid output (recorded for Interi patients only), and manifold/standard drain duration were retrieved and tabulated. Seroma was defined as clinically palpable or visible fluid. Summary statistics of the data, including mean, SD, and range, were performed for continuous variables, and frequency and percentages for categorical variables. All retrieved data were compared between the two groups. Statistical differences between groups were assessed using Fisher's exact test or the chi-square test for categorical variables and Students' *T*-test for continuous variables, setting the significance level at below 5%.

## RESULTS

### Study Participants

Forty-six consecutive patients who underwent immediate prepectoral breast reconstruction were included in this study: 23 patients received Interi and 23 patients received standard drains. Patients were not selected for each therapy. The Interi group consisted of the most recent 23 patients reconstructed in the author's practice between September 2020 and March 2021 when the author trialed this therapy. The standard drain group consisted of the last 23 patients reconstructed between April 2020 and November 2020 before trialing Interi. A total of 38 breasts were reconstructed in the Interi group, and 39 breasts were reconstructed in the standard drain group.

### Baseline Demographics and Mastectomy and Reconstructive Characteristics

Baseline demographic and comorbid characteristics as well as mastectomy and reconstructive variables of study patients are shown in Table 1. Patients in both groups were well matched in all variables with no significant differences between the groups. Overall, patients had a mean age of 51.8 years with a mean body mass index in the overweight range (27.8 $kg/m^2$). Diabetes was uncommon, while approximately a third had hypertension, and a third were obese. Skin-sparing mastectomy was more common in both groups, and about half of all mastectomies were for oncologic reasons; the remaining were prophylactic. A quarter of the patients had undergone neoadjuvant chemotherapy. The majority of reconstructions (almost 80%) were two-stage tissue expander reconstructions.

### Duration of Therapy and Fluid Volume

Among patients who received Interi, the manifold was removed at a mean of 16.7 days from each breast (Table 2). Mean volume of fluid collected per breast was 976.7 mL. Among patients who received standard drains, the drains were removed at a mean of 19.7 days (Table 2). Compared with Interi, duration of drains was significantly longer ($P = 0.020$). Data on mean volume of fluid collected from drains were not available because it was not routine practice to measure and document total volume collected.

### Postoperative Complications

Patients in the Interi group were followed for a mean of 155.7 days (±59.0 days; range: 64–274 days) from the date of surgery, which included a mandatory minimum of 14 days follow-up after manifold removal. The timeframe of 14 days was selected because seroma formation usually occurs within 1–2 weeks after drain removal. Patients in the standard drain group were followed for a mean of 337.2 days (±56.6 days, range: 204–421 days) from the date of surgery, which is significantly longer than in the Interi group ($P < 0.0001$). The longer follow-up in the standard drain group is to be expected because these patients were operated on before trialing Interi. All complications in the standard drain group, however, occurred by postoperative day 61, and all patients in the Interi group had at least 64 days of follow-up.

During the follow-up period, complications occurred in four breasts (10.5%) in the Interi group, and 14 breasts (35.9%) in the standard drain group; the difference was statistically significant (Table 3). Complications (Interi versus standard drain) included seroma after Interi/drain removal (0% versus 20.5%), flap revision (2.6% versus 15.4%), red breast (5.3% versus 7.7%), edematous flap (0% versus 2.6%), infection (2.6% versus 2.6%), implant/tissue expander loss (5.3% versus 5.1%), and failed reconstruction (0% versus 2.6%). None of these complications, with the exception of seroma, differed significantly between the groups. The rate of seroma was significantly higher in the standard drain group. There were no incidences of wound-related complications such as abnormal erythema, swelling, draining, or dehiscence at the manifold or drain exit sites.

**Table 1. Demographic, Comorbidity, Neoadjuvant/Adjuvant Therapy, and Mastectomy and Reconstructive Variables**

| Variables | Interi System | Standard Drains | Total Population | *P* (Interi versus Standard Drains) |
|---|---|---|---|---|
| No. patients | 23 | 23 | 46 | — |
| No. breasts | 38 | 39 | 77 | — |
| Age, mean ± SD, y (range) | 53.7 ± 11.5 (34–78) | 50.0 ± 12.1 (30–74) | 51.8 ± 11.9 (30–78) | 0.294 |
| Body mass index, kg/m$^2$ (mean ± SD, range) | 27.8 ± 4.4 (19.4–36.2) | 27.9 ± 6.1 (18.0–39.6) | 27.8 ± 5.2 (18.0–39.6) | 0.949 |
| Comorbidities, no. patients (%) | | | | |
| Diabetes | 1 (4.3) | 2 (8.7) | 2 (6.5) | 0.550 |
| Hypertension | 8 (34.8) | 5 (21.7) | 13 (28.3) | 0.326 |
| Smoking | 0 | 0 | 0 | — |
| Obesity | 9 (39.1) | 7 (30.4) | 16 (34.8) | 0.536 |
| Others | 8 (34.8) | 6 (26.1) | 14 (30.4) | 0.522 |
| None | 10 (43.5) | 11 (47.8) | 21 (45.7) | 0.767 |
| Mastectomy type, no. breasts (%) | | | | |
| Skin-sparing | 21 (55.3) | 26 (66.7) | 47 (61.0) | 0.305 |
| Nipple-sparing | 17 (44.7) | 13 (33.3) | 30 (39.0) | 0.305 |
| Oncologic | 21 (55.3) | 21 (53.8) | 42 (54.5) | 0.901 |
| Prophylactic | 17 (44.7) | 18 (46.2) | 35 (45.5) | 0.901 |
| Laterality, no. patients (%) | | | | |
| Unilateral | 8 (34.8) | 7 (30.4) | 15 (32.6) | 0.753 |
| Bilateral | 15 (65.2) | 16 (69.6) | 31 (67.4) | 0.753 |
| Mastectomy specimen weight per breast, mean ± SD (range), g | 614.1 ± 315.4 (97–1238) | 699.8 ± 535.3 (117–1984) | 657.5 ± 440.0 (97–1984) | 0.396 |
| Reconstruction type, no. breasts (%) | | | | |
| Direct-to-implant | 9 (23.7) | 7 (17.9) | 16 (20.8) | 0.535 |
| Tissue expander/implant | 29 (76.3) | 32 (82.1) | 61 (79.2) | 0.535 |
| Tissue expander fill volume, mean ± SD (range) per breast, mL | | | | |
| Oncologic breast | 343.8 ± 190.5 (0–600) | 236.1 ± 191.6 (0–500) | 286.8 ± 195.9 (0–600) | 0.111 |
| Prophylactic breast | 340.9 ± 223.4 (0–600) | 196.4 ± 183.4 (0–500) | 250.0 ± 212.6 (0–600) | 0.089 |
| Implant volume per breast, mL (mean ± SD range) | 440 ± 150.6 (190–605) | 505.7 ± 169.1 (360–750) | 468.8 ± 157.1 (190–750) | 0.425 |
| Neoadjuvant chemotherapy, no. patients (%) | 6 (26.1) | 6 (26.1) | 12 (26.1) | 1.000 |
| Axillary dissection, no. breasts (%) | 2 (5.3) | 3 (7.7) | 5 (6.5) | 0.665 |

## DISCUSSION

Efficient fluid removal and approximation of internal tissue planes is critical for seroma prevention and tissue healing. Currently available approaches—standard drains and sutures—to address postsurgical wound control have not demonstrated meaningful or consistent success. Standard drains and bulbs rely on gravity or hand pumps, and provide limited and inconsistent tissue closure and fluid evacuation as they deliver inconsistent and diminishing negative pressure. In addition, each standard drain only accesses one area of the internal site, although multiple drains may be used to access additional internal sites but this requires multiple exit sites. Further, patient intervention is required to frequently empty and recharge bulbs. Sutures (layered, mattress, or quilting), on the other hand, have no fluid evacuation capabilities.

The Interi System was developed in an attempt to fill the clinical need for a more efficient approach to postsurgical wound control and fluid evacuation. Interi is unique in that it is an internal negative pressure delivery system and has an internal branching manifold. Although negative pressure systems have been in use since the late 1900s,[9] these are external devices. Referred to as negative pressure wound therapy, they are applied externally on closed incisional wounds to promote drainage and tissue healing at the incision site, so as to prevent surgical site complications.[10,11] In breast reconstructive surgery, surface negative pressure wound therapy is sometimes used in conjunction with standard drains.[12] Interi, in contrast, delivers negative pressure to internal tissue planes where fluid collects to approximate tissue planes and simultaneously evacuate the fluid from these internal spaces. In addition, Interi's unique internal branching manifold, with up to four branches, ensures broad coverage of internal tissue planes, for more efficient negative pressure delivery and fluid evacuation. Despite having four branches, the manifold is exited from the surgical area through a single exit site.

**Table 2. Duration of Therapy and Fluid Output**

| Variable | Interi System | Standard Drains | *P* |
|---|---|---|---|
| Duration of therapy per breast, mean ± SD, d (range) | 16.7 ± 3.5 (9–26) | 19.7 ± 7.0 (9–44) | **0.020** |
| Fluid collected per breast mean ± SD, mL (range) | 976.7 ± 355.5 (390–1885) | Not available | — |

Bold values indicate statistical significance.

**Table 3. Postoperative Complications**

| Complication | Interi System, n (%) (N = 38) | Standard Drains, n (%) (N = 39) | *P* |
|---|---|---|---|
| Seroma* | 0 | 8 (20.5) | **0.005** |
| Flap revision | 1 (2.6) | 6 (15.4) | 0.108 |
| Red breast | 2 (5.3) | 3 (7.7) | 1.00 |
| Edematous flap | 0 | 1 (2.6) | 1.00 |
| Infection | 1 (2.6) | 1 (2.6) | 1.00 |
| Implant/tissue expander loss | 2 (5.3) | 2 (5.1) | 1.00 |
| Failed reconstruction | 0 | 1 (2.6) | 1.00 |
| Any complication | 4 (10.5) | 14 (35.9) | **0.014** |

*After Interi System/standard drain removal.

This retrospective study, which trialed the use of Interi in prepectoral breast reconstruction, found Interi to be a safe and effective therapy. Fluid was effectively evacuated with no instances of seroma formation after removal of the manifold. In addition, there were no instances of edematous flap or reconstructive failure. There were also no device-related safety concerns. Three patients (four breasts) reported clogging of the system, which was resolved by stripping the tubing and clearing the clot from the connector. There was one instance of fluid collection while on therapy, which was observed in the first patient who received Interi. The patient was seen on postoperative day 6 with fluid collection behind the expander, which the author believes may be due to not placing a manifold branch in this space. The issue was resolved by drainage and expander expansion to fill the space. After this incidence, one of the manifold branches was placed behind the prosthesis in all subsequent reconstructions with no further instances of fluid collection in this space during therapy.

Compared with patients who received Interi, patients who received standard drains had a significantly higher incidence of seroma formation after drain removal. All seromas occurred inferiorly or infero-laterally in these patients and were resolved after drainage. In one breast, a subsequent Staphylococcus infection resulted in implant removal and replacement. In another breast, the implant was removed per patient request after seroma resolution, although cultures from this breast were negative.

An interesting finding in this study was the significantly shorter duration of therapy with Interi compared with standard drains. This raises the question of whether the shorter duration of Interi use was due to more efficient fluid evacuation and wound control. Unfortunately, this study was not able to answer this question because the volume of fluid discharged from standard drains was not recorded for a comparative analysis.

In the author's experience, Interi was easy to handle and deploy intraoperatively. The internal manifold was well-tolerated by patients with no reports of discomfort or pain. Patients also found the device easy to use; they had no issues with respect to changing the therapy units. Although the actual cost of Interi exceeds that of standard drains, the use of Interi can be justified by the significant reduction in complications, especially seroma (as observed in this study), which may have overall implications for the total cost of care and patient satisfaction.

This study is limited by the retrospective study design and the relatively small patient numbers. Notwithstanding these limitations, the encouraging results from this study merit further prospective, controlled studies to evaluate the safety and effectiveness of utilizing Interi to evacuate fluid from internal tissue planes to prevent seroma formation.

## CONCLUSIONS

The Interi System, a novel internal negative pressure system, appears to be a safe and effective system for the prevention of seroma formation following breast surgery. Interi effectively removed fluid from internal tissue compartments in prepectoral breast reconstruction, as evidenced by the output volume and the absence of seroma formation after therapy discontinuation. There were no wound healing issues associated with the use of Interi. Its unique design of a branched manifold provides broad coverage of internal tissue planes. Interi may offer significant improvement over current standards of care by more effectively closing down internal tissue planes and removing excess fluid from subcutaneous spaces.

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