



INCISIONS & INSIGHTS



Reshaping Breast Reconstruction

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Manufacturers continuously engineer, innovate and refine implant technology in an ongoing effort to provide devices that will help deliver improved patient outcomes. Breast tissue expanders are no exception. As a surgeon that performs over 350 breast reconstructions annually, I, like many of you, find acceptance of change to be very difficult. However, when I saw the advancement of the MENTOR® ARTOURA™ Breast Tissue Expander I was eager to give it a try. Through several case examples I hope to leave you with some technical pearls as well as demonstrate the versatility and differentiated results our practice has achieved using the ARTOURA Expander in breast reconstruction.

INTRODUCTION:

There are many challenges in creating a natural reconstructed breast, some of which include, but are not limited to:

- Difficulty simulating the natural shape of the breast after mastectomy
- Predictable breast footprint
- Limited inferior pole expansion compounded by over-expansion of the superior pole
- Excessive lateral pole expansion
- The need for extensive capsule release and contouring work intra-operatively in order to achieve a natural lower pole.

Breast reconstruction using traditional expanders has been performed for nearly half a century and over the years continued evolution has improved outcomes. Development of features such as integrated ports, suture tabs, and the upper pole Bufferzone® Self-Sealing Patch have helped with many of these difficulties, but the issues of a slightly ptotic lower pole, and unencumbered upper and lateral pole expansion have not been addressed...until now.

In our practice, we have found that the ARTOURA Expander has addressed many of these issues by virtue of its internal expansion framework (See Figure 1). Since incorporating ARTOURA Expanders we have experienced several benefits.

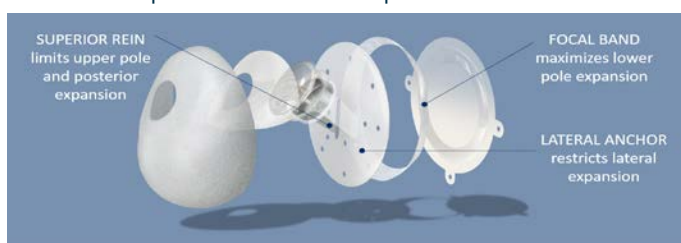


Figure 1

First, more predictable results during tissue fills, which gives reproducible final shapes that are less dependent on the initial mastectomy surgery, patient habitus and anatomy. By restricting upper and lateral pole expansion, the ARTOURA Expander results in a more natural expansion and breast shape from the very beginning of the reconstructive process. Patient body image can be a very difficult issue for patients, and a more natural breast shape pre-implant makes the patient feel more “normal” sooner in the reconstruction process. Secondly, less unwanted superior pole expansion and more inferior pole expansion, which is generally the most difficult area of the pocket to expand, allows the creation of a more natural breast shape during expansion. Before ARTOURA Expanders, there could be extensive capsule release necessary to create enough inferior pole expansion. This capsule work has to be done during the implant placement surgery, making the final results less predictable. Being able to attain a more natural shape earlier in the reconstruction process requires less structural work during the procedure, which in turn decreases the patient’s time under anesthesia. After all, the lateral and upper pole areas expand uncontrolled with other expanders because it is the area of least resistance. Only something built into the expander itself can limit this. The superior rein, lateral anchor and focal band in the ARTOURA Expander ensures controlled anterior projection and limits lateral expansion that was common in the previous expander generations. Finally, this also addresses expansion into the axilla which was a common patient comfort concern late in the expansion process. We will demonstrate examples of several results using the ARTOURA Expander for breast reconstruction.

CASE 1

This is a 46 y/o patient that presented with a BRCA mutation. She elected to undergo a bilateral nipple sparing mastectomy with tissue expander placement and ADM. In the past we would have chosen expanders with base widths ~ 1cm less than the patient base width, but due to the predictable footprint provided by the ARTOURA Expanders we chose a close match to the patient's existing base width. For this patient, expander selection was 650cc Ultra High ARTOURA Expanders, which have a 13.0cm width. The ARTOURA Expander provided the ability for the inferior pole to expand naturally without having to worry about the superior pole over expanding, making implant selection easy, especially with advent of MENTOR® MemoryShape® Breast Implants. The pocket created by the ARTOURA Expander is a similar shape and match to the MemoryShape Breast Implants resulting in greater predictability in the final result. In addition, not needing to reset the inframammary fold and recruit upper abdominal skin results in fewer complications including skin tethering, pain, and implant bottoming out/malposition. After approximately 3 months of expansion, she underwent removal of her tissue expanders, and placement of 620cc MH MemoryShape® Breast Implants with fat grafting.



CASE 2

This 66 y/o patient presented with bilateral breast cancer. She elected to have bilateral mastectomies with immediate two stage expander to implant reconstruction. At the time of her mastectomies, 700cc Ultra High ARTOURA Expanders were used (13.5cm width) along with a 6x16 sheet of acellular dermal matrix. This patient had short breast footprints with large mastectomy skin flaps. In these patients skin envelope reduction is necessary to match the expander and prevent contour irregularities and seroma formation. The options for envelope reduction include delaying her reconstruction or significant skin reduction at the time of the mastectomy. As opposed to the standard elliptical excision in which contouring of the medial and lateral portion of the breast is difficult, we elected to primarily use her superior skin flap, and excise the lower skin flap to make the incision line in the IMF. Using the ARTOURA Expanders we had confidence that lower pole expansion could still be achieved despite not having the innate lower skin flap. The expansion process took 4 months. Expanders were filled intra-op to 120cc's and the ending fill volumes were right breast 700cc's and left breast 680cc's. Expanders were exchanged with 685cc MH MemoryShape Breast Implants. Five months post-op 3-D nipple areola tattoos were done. Significant expansion was achieved in the lower pole which provided a natural result, desired elevation of the breast footprint and an incision concealed in the inframammary fold.



CASE 3

The third case example is a 58 year old patient with history of prior right lumpectomy with adjuvant radiation treatment who presents with a recurrence of her breast cancer and elects to undergo bilateral mastectomy with reconstruction. Due to her desire for a larger cup size, she elected implant reconstruction as opposed to autologous reconstruction via a DIEP flap. In addition, due to her prior right whole breast radiation and the subsequent fibrosis, we recommended a right latissimus flap with bilateral tissue expander reconstruction with nipple-areola preservation. A skin island was used to help restore symmetric nipple positions, and although the breast/expander complex has significant discrepancies (i.e.



Pre-Op



Post-Op



sub pectoral vs. sub-latissimus and prior radiation to right breast), the fixed footprint and expansion of the ARTOURA Expander allowed for a balanced look in two different settings. She ultimately had her expanders exchanged for Ultra High MENTOR® MemoryGel® Breast Implants (right - 535 cc, left - 700 cc) and autologous fat grafting.

ADDITIONAL CASES

*Nipple sparing mastectomy with ARTOURA UH Expanders:
 49 y/o Left: 535cc Right: 535cc
 MemoryShape Breast Implants:
 Left: 555cc MH Right: 555cc MH*



Pre-Op



Post-Op

*Large, short footprint breasts pre-op with ARTOURA UH Expanders:
 69 y/o Left: 700cc Right: 700cc
 MemoryGel® Breast Implants
 Left: 800 UH Right: 800 UH*



Pre-Op



Post-Op

Bilateral nipple sparing mastectomies, ARTOURA Expanders, MemoryShape Breast Implants

*44 y/o, ARTOURA UH Expanders
 Left: 455cc Right: 455cc
 MemoryShape Breast Implants
 Left: 390 MH Right: 390 MH*



Pre-Op



Post-Op

*52 y/o, ARTOURA HP Expanders
 Left: 600cc Right: 600cc
 MemoryShape Breast Implants
 Left: 620 MH Right: 620 MH*



Pre-Op



Post-Op

CONCLUSION:

In conclusion, the ARTOURA Expander can provide consistent predictable results in a wide variety of patient types and surgical procedures. Whether prior radiation or a patient desiring nipple-areola preservation, in our experience the predictable pocket creation by the ARTOURA Expander results in a natural shape that mimics the highly cohesive gel anatomic implants and produces excellent aesthetic results. Although ARTOURA Expanders are similar to past expanders it is also important to recognize that they are still unique devices and your technique may need to adapt accordingly. After performing and closely following more than 25 cases, specific pearls include; (1) Select your expander width based on final desired breast width. Do not undersize and over expand as you may have done with past generation devices. The footprint will not change. (2) Initial expander fill volume should be adequate to eliminate space. As with all devices this will reduce the risk of seroma formation. (3) Secure at least 2 suture tabs to minimize the risk of migration and/or rotation. Overall, we have been extremely pleased with the outcomes and minimal complications experienced to date using ARTOURA Expanders.

DISCLAIMER:

This white paper includes a demonstration of the use of a surgical device; it is not intended to be used as a surgical training guide. Other surgeons may employ different techniques. The steps demonstrated may not be the complete steps of the procedure. Individual surgeon preference and experience, as well as patient needs, may dictate variation in procedure steps. Before using any medical device, including those demonstrated or referenced in this white paper, review all relevant package inserts, with particular attention to the indications, contraindications, warnings and precautions, and steps for use of the device.

IMPORTANT SAFETY INFORMATION:

MENTOR® MemoryGel® Breast Implants, MENTOR® MemoryShape® Breast Implants, and MENTOR® Saline-filled Breast Implants are indicated for breast augmentation in women (at least 22 years old for MemoryGel® Implants and MemoryShape® Implants, and 18 years old for Saline Implants) or for breast reconstruction. Breast implant surgery should not be performed in women with active infection anywhere in their body, with existing cancer or pre-cancer of their breast who have not received adequate treatment for those conditions, or who are currently pregnant or nursing.

Breast implants are not lifetime devices and breast implantation may not be a one-time surgery.

The most common complications for breast augmentation and reconstruction with MemoryGel® Implants include any reoperation, capsular contracture, and implant removal with or without replacement. The most common complications with MemoryShape® Implants for breast augmentation include reoperation for any reason, implant removal with or without replacement, and ptosis. The most common complications with MemoryShape® Implants for breast reconstruction include reoperation for any reason, implant removal with or without replacement, and capsular contracture. A lower risk of complication is rupture. The health consequences of a ruptured silicone gel breast implant have not been fully established. MRI screenings are recommended three years after initial implant surgery and then every two years after to detect silent rupture.

The most common complications with MENTOR® Saline-filled Implants include reoperation, implant removal, capsular contracture, breast pain, and implant deflation.

For MemoryGel® Implants, patients should receive a copy of Important Information for Augmentation Patients about MENTOR® MemoryGel® Breast Implants or Important Information for Reconstruction Patients about MENTOR® MemoryGel® Breast Implants. For MemoryShape® Implants, patients should receive a copy of Patient Educational Brochure – Breast Augmentation with MENTOR® MemoryShape® Breast Implants or Patient Educational Brochure – Breast Reconstruction with MENTOR® MemoryShape® Breast Implants, and a copy of Quick Facts about Breast Augmentation & Reconstruction with MENTOR® MemoryShape® Breast Implants. For MENTOR® Saline-filled Implants, patients should receive a copy of Saline-Filled Breast Implants: Making an Informed Decision. Your patient needs to read and understand the information regarding the risks and benefits of breast implants, with an opportunity to consult with you prior to deciding on surgery.

The ARTOURA™ Breast Tissue Expander or CONTOUR PROFILE® Breast Tissue Expander can be utilized for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision, and tissue defect procedures. The expander is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months. Do not use the ARTOURA™ Tissue Expander nor CONTOUR PROFILE® Tissue Expander in patients where an MRI may be needed. The device could be moved by the MRI causing pain or displacement, potentially resulting in a revision surgery. The incidence of extrusion of the expander has been shown to increase when the expander has been placed in injured areas.

For detailed indications, contraindications, warnings, and precautions associated with the use of all MENTOR® Implantable Devices, which include MENTOR® Saline-filled Implants, MemoryGel® Implants, MemoryShape® Implants, ARTOURA™ Expanders, and CONTOUR PROFILE® Expanders, please refer to the Product Insert Data Sheet provided with each product or visit www.mentorwwllc.com.