



INCISIONS & INSIGHTS



ARTOURA™ Breast Tissue Expanders and MemoryShape® Breast Implants: *Expanding Your Reconstruction Toolbox*

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Introduction:

There was a time when breast reconstruction patients were content with simply having a breast mound or looking good in clothes; that time has passed. Many of today's patients expect to look just as good or better than they did pre-mastectomy. They want breasts with a well defined IMF, curvilinear lower pole contour and a near-even distribution of implant volume i.e. upper and lower pole fullness without a round, overly augmented appearance to the breast. To meet the rising expectations of today's patient, plastic surgeons need better "tools" to overcome the challenges created by the mas-

tectomy such as thin skin envelope and ablated architecture/support structures such as lateral and inframammary folds. This article will discuss two tools: (1) The ARTOURA Expander and (2) The MemoryShape Implant. After reading this article one should be familiar with the clinically salient features of the ARTOURA Expander, able to identify the patients best suited for the expander, comfortable with the different approach to choosing the expander, expansion and implant exchange and how it differs from older generation expanders.

CONTROL: The ARTOURA Expander Difference

The ARTOURA Breast Tissue Expander is the only expander with Dynamic Control Technology™ designed to prevent unwanted dimensional changes for a more consistent and desirable result. So what does this mean for the clinician? The added technology of the superior rein allows for some superior expansion, however it directs the majority of expansion force to the lower pole. (Fig.1) The lateral anchor



Figure 1

and focal band restrict uncontrolled lateral and medial expansion to produce a pocket with a stable base diameter (width) and a fuller more “natural appearing” lower pole i.e. improved lower pole arc and defined inframammary fold (Fig.2a,2b,2c). These characteristics of a stable base diameter and the concentrated lower pole expansion, affect every aspect of the reconstruction process; from patient-expander selection, to expansion to implant exchange.



Figure 2: A,B



Figure 2C

- More concentrated in lower pole
- Better IMF definition

Patient-Expander Pairing

During my training, we used a previous generation of expander, which was an omnidirectional expander; meaning it would expand equally in all directions. That one quality influenced my whole approach to breast reconstruction: I chose an expander with a smaller base diameter than the final breast width because I knew that during the expansion process, the device would expand radially (base width) as well as vertically (projection). I over-expanded, 15-25%, in order to get the desired base diameter as well as increase projection. The problem that frequently arose was this: in order to achieve the desired base width, I had to create an over projected pocket. The excess tissue in the AP vector (projection) was too great for any implant to fill. The unused space, when not filled, falls (for lack of better term) and effectively increases the base diameter. For example, a 550cc expander, at nominal fill, has a base diameter of 13.5cm and projection of 7.4cm, but the 550cc high profile implant has a projection of 5.5cm. What happens to extra 1.9cm of projection? It effectively increases the base diameter. One can get the idea by looking at the volume of two cones, cone A and cone B, the surrogates

for an expanded skin envelopes. If one assumes a constant volume, then decreasing the height, our surrogate for projection, the radius or base diameter must increase for the volume to remain the same (Fig.3).

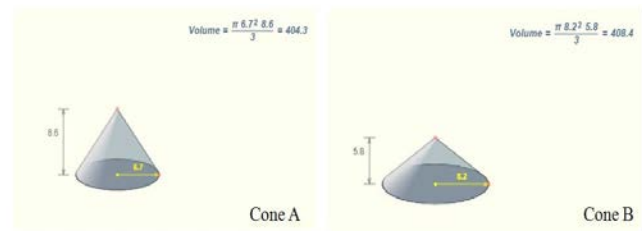


Figure 3

On the other hand, the ARTOURA Expander has a set base diameter, due to the lateral anchor, even at lower fill volumes. Because of the stable base diameter, the bulk of the expansion is in the AP direction and the base width is unaffected. Therefore, the surgeon should choose the expander with a base diameter closest to that of the desired post-op breast when using ARTOURA Expanders.

Placing the Expander

The first stage of reconstruction, placing the expander, differs when using the ARTOURA Expander. Given the multi-directional expansion profile of older expanders, their initial placement was less precise. I would place the deflated expander with the base along the inframammary fold and centered over the breast meridian, securing all three tabs with 2.0 PDS for added stability. I counted on the expansion process to set the base diameter and any malformation of the pocket would be addressed at the second stage.



Figure 4: A,B

With the ARTOURA Expander, the lateral anchor and focal band create a stable footprint with respect to the base diameter, so precise placement is important. Consequently, I changed my first stage approach in the following ways: (1) I place the partially inflated expander in the subcutaneous pocket, noting the position that produces the best shape, especially the medial lower pole (2) The location of the

Expansion

The technical aspects of expansion are the same with both the ARTOURA Expanders and older generation expanders. Pain with expansion is very subjective with either device. However, the character of the expansion pain is different in patients with the ARTOURA Expander. With previous generation expanders, the pain was non-localized, felt over the entire expanded breast, but because of the preferential lower pole expansion of the ARTOURA Expander, when my patients reported discomfort it was localized predominantly to the lower pole of the breast, and the inframammary fold. As is the case with all expander pain, it resolves within 24hrs and is treated with NSAIDS or muscle relaxer, if needed, and reassurance. In fact, once I explained to the patients the reason for the localized discomfort, showing them in the mirror the degree of lower pole expansion, they understood and were relieved. With the stable base width and only expansion in the AP direction I have also recognized that lower total fill volumes are required prior to the second stage (Fig.6). Before ARTOURA Expanders, the nursing staff and PA, those who usually handle the expansion process, would expand weekly until they had overexpanded by 10%. Then, I would see the patients prior

3, 6, and 9 o'clock tabs are marked on the skin (Fig.4a,4b) (3) A small subcutaneous tunnel, 1cm wide and 2cm long, is created below the inframammary fold (4) a marionette suture (1.0 Prolene) is used to pull the 6 o'clock tab into the tunnel, making sure the base of the expander is snug against the lower pole (Fig.5) (5) the pectoralis, which is

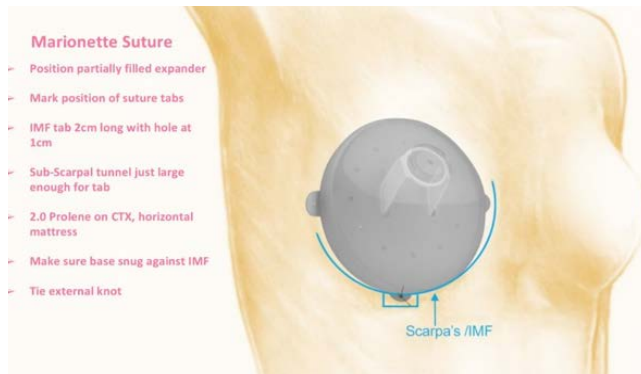


Figure 5

partially released, is freed off of its costal insertion enough to accommodate the most medial aspect of the expander (6) All three tabs are secured to chest wall with 2.0 PDS to minimize rotation. Precise expander placement at the first stage may take more time, but it creates a predictable pocket that requires little to no capsule modification, saving time at the second stage.

to their last expansion. Since using the ARTOURA Expanders, I examine the patients when they are approximately 50-100cc away from the expander 's nominal fill volume in order to assess the quality of the lower pole skin and gauge the amount of subsequent expansion, if any, that needs to be done.

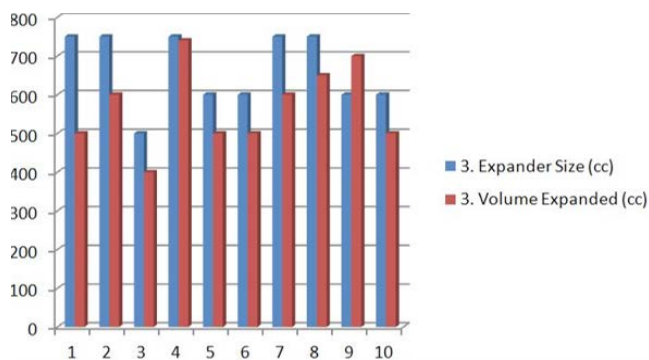


Figure 6: *Ten patients from the ARTOURA™ Breast Tissue Expander Early Experience Survey.

Implant Control

The second stage of reconstruction, implant exchange, has changed dramatically since incorporating the ARTOURA Expander into my practice. As previously stated, with older devices the pocket was unreliable and had to be overfilled to achieve an adequate base diameter. This led to an over-projected pocket, with unused AP skin, effectively increasing the base diameter. Consequently, one has to either use a larger implant or extensively modify the pocket in any number of ways: lateral capsulorrhaphy or capsular flaps to prevent lateralization, inferior capsulorrhaphy to reposition or improve inframammary fold definition, and capsulotomy to allow the implant to descend and increase lower pole volume. If one underfilled an older expander, then they would have to perform extensive anterior and lateral capsulotomies to increase projection, lower pole volume, and base diameter. The utilization of widespread capsulotomy, in my experience, leads to an unstable pocket and subsequent implant malposition such as lateralization, bottoming out or other asymmetries in volume distribution. I have found that the ARTOURA Expander produces a pocket that requires little modification. In my experience, less manipulation translates to increased capsule integrity and a stronger, more stable scaffold to support the im-

plant. The ARTOURA Expander pocket creates a “hand in glove” fit, particularly when paired with the MemoryShape Implants. I now only release the pocket superiorly and medially (10 o’clock to 3 o’clock) at the beginning of the case. This serves two purposes: (1) it provides a raw surface for the textured implant to adhere to and (2) a small amount of laxity that will accommodate small variations in implant selection i.e. .5 to 1cm. If more release is needed then I do so in a step-wise, incremental fashion: (1) medial and then (2) upper 2/3 of lower pole and (3) lateral is last. Lower pole and lateral capsulotomies are carried out only if absolutely necessary. I do the least amount of pocket manipulation as possible in order to preserve structural integrity.

When selecting implants for the second stage, the base diameter of the expander is my starting point. I will then choose implants two sizes up in two different profiles, depending on the fill volume and the patient’s desired results. For example, a 500cc ARTOURA Expander with a base diameter of 13.5cm will produce a pocket that can accommodate a 555cc or 620cc MH if underfilled, but also a 555cc-615cc TM+ if filled to its nominal volume.

The following cases illustrate a high degree of agreement between expander and implant.

Case 1

32 y/o female s/p NSSM and DTI reconstruction with 495cc TM+ MemoryShape Implants. She had total NAC loss on the right and partial on the left. The right implant had to be removed and a 500cc High Profile ARTOURA Expander placed and expanded to 450cc.



500cc HP ARTOURA Expander is on the patient’s right and a 495cc TM+ MemoryShape Implant is on the patient’s left.

At the time of expander exchange the patient wanted a slightly larger implant so 555cc TM+ MemoryShape Implants were placed bilaterally.



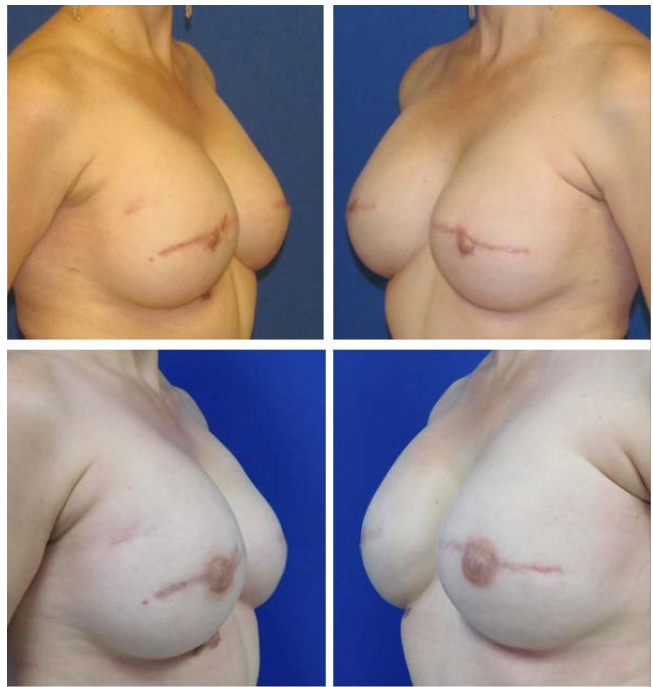
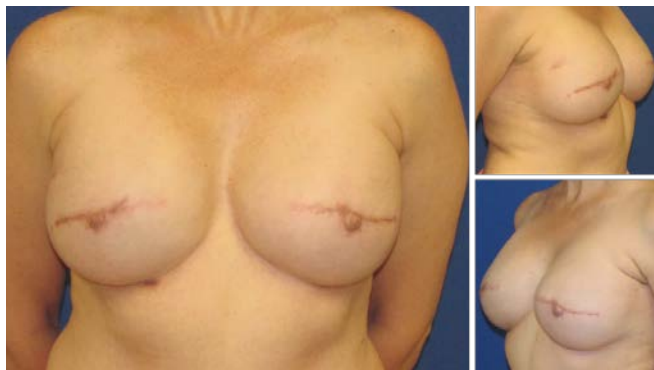
The underfilled 500cc HP ARTOURA Expander with a base diameter of 13.5cm was able to accommodate a 555cc TM+ MemoryShape Implant with a base width of 14cc with only superior and medial capsulotomy.

Case 2

45 y/o female presented for delayed reconstruction. She desired a “tastefully augmented” post-operative appearance. 500cc HP ARTOURA Expanders were placed and expanded to their nominal fill volume.



At the second stage 620cc MH MemoryShape Implants were placed.



9 month post-op, stable implant position, and breast appearance.

The 500cc HP ARTOURA Expander with a base width of 13.5cm at nominal fill was able to accommodate a 620 MH MemoryShape with a base width of 14cm with only superior and medial capsulotomy. With minimal pocket dissection, there is a stable scaffold for the implant conferring durable positioning and an aesthetic result.

Conclusion

The ARTOURA Expander is a new tool for the breast reconstruction surgeon. It allows the surgeon more pocket control with focused lower pole expansion and a stable base diameter. There are fewer fills required for pocket creation, and the pocket requires less manipulation translating into increased structural integrity of the capsule and less OR time. The stronger support means more predictable and durable results for better aesthetic outcomes. The ARTOURA Expander's design, with restrained upper pole expansion, focused lower expansion, and stable base width, produces a hand in glove fit, especially when paired

with the portfolio of MemoryShape Implants. Surgeons, by nature, are creatures of habit. We find what works and tend to stay with it. It makes us more efficient, but changing patient expectations and new technology can force us out our comfort zone in order to achieve better outcomes. To make the transition easier for incorporating the ARTOURA Expander, I've included the following “Pearls”; lessons I've learned over the past year and a half after having completed 40+ cases.

Pearls

1. Start with lower BMI patients with smaller breast or deflated breast with a narrower breast width.
2. Pick your expander based on final desired base width of the breast. Measure the ideal base like you would for an augmentation, but realize that there is no contribution from the soft tissue i.e. medial and lateral pinch.
3. Plan on extra time for the first stage while you are initially getting used to the expander. Place the partially filled expander into the subcutaneous pocket to determine the best position. 10-15 degrees of medial rotation is acceptable if it produces a better shape. Make sure the inferior base is abutting the inframammary fold and secure the expander with the tabs to prevent rotation.
4. Follow the first 10 expansions until you are comfortable with the expander and then see patients when they are 50-100cc away from the nominal fill.
5. Choose a couple different sizes of implants (usually one or two sizes up) using the base width of the expander as your starting point.
6. Manipulate/release the capsule as little as possible, starting superiorly from 10-3 o'clock. This will allow for some increased pocket laxity, to accommodate different implant profiles and base widths, as well create a raw surface for the implant to adhere to.

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 [HYPERLINK "http://www.mentorwllc.com"](http://www.mentorwllc.com) www.mentorwllc.com.