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The information contained in this manual will assist you in understanding how the Brava® Breast Enhancement and Shaping System works, the changes your body will experience, and the underlying biological reasons for these changes. This manual will also instruct you on how to get the greatest benefit from using the System and how to take care of its various components. PLEASE REVIEW THE FOLLOWING SECTION FOR APPLICABLE WARNINGS AND PRECAUTIONS BEFORE USING THE BRAVA SYSTEM.

The terms *Brava®*, *Brava®* System, *Brava®* Sport and *Brava®* Starter System all refer to the family of *Brava®* System products and are used interchangeably throughout this manual.

WARNING: READ BEFORE WEARING DEVICE

Warnings

- DISCONTINUE USE IF YOU EXPERIENCE SIGNIFICANT DISCOMFORT, PAINFUL SWELLING, SKIN IRRITATION, REDNESS, ITCHING OR TENDER RIBS/STERNUM.
- MOVE TO A DEEPER DOME SIZE OR DISCONTINUE USE IF THE NIPPLE OF YOUR BREAST REACHES WITHIN 1/2" INCH OF TOUCHING THE DOME.
- DO NOT WEAR WHILE SHOWERING, BATHING, SWIMMING, OR DURING ANY OTHER WATER-RELATED ACTIVITY.
- THE *BRAVA®* SYSTEM SHOULD NOT BE WORN BY WOMEN WHO ARE NOT FULLY DEVELOPED (UNDER THE AGE OF 18) OR THOSE WOMEN WHO ARE/HAVE:

PREGNANT: Use of the *Brava®* System may begin 3-months after giving birth unless breastfeeding.

BREASTFEEDING: Use of the *Brava®* System can begin as early as 3-months after terminating breast-feeding; however, in some cases lactation can occur; therefore, it is suggested that use begin 3 months post lactation.

FAMILY HISTORY OF BREAST CANCER (MOTHER or SISTER): If your mother or sister was diagnosed with pre-menopausal breast cancer (breast cancer occurring before the menopause), then <u>we do not recommend wearing the Brava System</u>. If your mother or sister was diagnosed with post-menopausal breast cancer (breast cancer occurring after menopause), you may use the System after you complete <u>a screening mammogram and a</u> <u>breast exam</u>. These guidelines are recommended prior to use and are currently used by plastic surgeons prior to any type of cosmetic breast surgery.

HISTORY OF AN ABNORMAL MAMMOGRAM OR BREAST BIOPSY

HISTORY OF SEVER PAINFUL FIBROCYSTIC BREAST CHANGES

A CURRENT BREAST MASS (LUMP) OR CYST

A HISTORY OF RADIATION TO THE CHEST AREA, OTHER THAN ROUTINE X-RAYS

CHRONIC ACNE, ECZEMA, HYPERPIGMENTATION, OTHER SKIN CONDITIONS INVOLVING THE CHEST AREA OR HAVE AN ALLERGY TO SILICONE

TAKING NARCOTIC PAIN MEDICATIONS, BLOOD THINNERS, ABUSING ALCOHOL, OR USING ILLEGAL SUBSTANCES

PRONE TO KELOID FORMATION

- A MASTOPEXY, REDUCTION MAMMOPLASTY: Use of the Brava System should not begin until 6 months have elapsed since the surgery. * (see disclaimer)
- **IMPLANT REMOVAL SURGERY:** Use of the *Brava* System should not begin until 3 months have elapsed since the surgery.* (see disclaimer)
- ASYMMETRICAL BREASTS AND/OR INVERTED NIPPLES: The Brava® System may be used.** (see disclaimer)
- **BREAST BIOPSY:** Use of the *Brava* System should not begin until 3 months after breast biopsy and as long as results were shown to be benign.*
- **BREAST CYST ASPIRATION:** Use of the *Brava* System should not begin until 1-month after aspiration.

*Disclaimer: Some individual physicians have noted a positive effect with regards to using the Brava System after implant removal. There have been no formal clinical studies showing any positive or negative effect conducted by Brava, LLC. NOTE: Existing scars may increase in size and/or become more pronounced.

****Disclaimer:** Some individual physicians have noted a positive effect on the treatment of asymmetry of the breast. Brava, LLC makes no claims regarding the treatment of asymmetrical breasts or inverted nipples. No clinical studies have been conducted to show any benefit positive or negative.

Precautions

- This product is designed to be comfortable to wear. If any signs of discomfort occur while you are wearing the *Brava®* System, remove it and contact *Brava* Customer Care (U.S.) at 1-800-407-5304. For any medical questions, please contact your healthcare provider.
- The part of the *Brava* System that comes into contact with the skin (dome's tacky sole) is covered by hypoallergenic material that has been tested for prolonged skin contact; however, it is highly recommend that the *Brava®* Skin Care Line be used daily for extra skin protection and that the *Brava* Dome Cleanser be used to extend the life of the domes. Contact *Brava* Customer Care (U.S.) at 1-800-407-5304 for more details.
- You should stop wearing the system immediately if you develop symptoms of sternum or rib tenderness, moderate to severe itching, painful swelling, skin redness, or irritation.
 Contact your health care provider for any medical questions.
- The domes are made of materials that should not be punctured, sliced, or stored at temperatures below -35 F or above 120 F. Avoid placing the domes in a location with severe temperatures (such as a car's trunk in summer weather) as the System could become damaged.

Adverse Reactions

The potential adverse reactions, which are usually temporary, that have been observed in some women include:

- Redness, heat rash and skin irritation
- Itching
- Excessive sweating
- Temporary increased or decreased sensitivity of the nipples
- Temporary discoloration of the skin
- Hyperpigmentation (darkening of the skin)
- Costochondritis, a rare cause of chest wall pain occurring in the costal cartilages of the rib cage (where the ribs connect to the breast bone)
- Tietzes Syndrome (painful rib swelling), prolong wear of the *Brava* System may be associated with painful rib swelling, an inflammatory condition which is self-limited.

IMPORTANT INFORMATION

THE *BRAVA®* SYSTEM REQUIRES A CONSISTENT WEAR REGIMEN OF A MINIMUM OF 10 CONSECUTIVE HOURS A DAY, EVERY DAY, FOR AT LEAST 10 CONSECUTIVE WEEKS TO ACHIEVE EFFICACY. DUE TO BIOLOGICAL VARIABILITY, A HIGHER INTENSITY OF WEAR AND LONGER WEAR TIME MAY BE NEEDED TO ACHIEVE DESIRED RESULTS.

FAILURE TO COMPLY WITH THE PROTOCOL WILL REQUIRE A LONGER WEAR PERIOD OR PRODUCE SUBSTANDARD RESULTS.

THE BRAVA SYSTEM MAY NOT BE SHARED. PROLONGED CONTACT WITH SOMEONE ELSE'S BACTERIAL FLORA COULD CAUSE INFECTION, ABSCESSES, SKIN BREAKDOWN, AND BLISTERING.

REMOVE IT IMMEDIATELY AT THE SIGN OF SIGNIFICANT ITCHING, DISCOMFORT, BURNING, AND/OR PAIN IN THE RIBS OR STERNUM.

THE *BRAVA* SYSTEM SHOULD BE COMFORTABLE TO WEAR. YOU ARE ENCOURAGED AFTER THE INITIAL 2 WEEKS OF 10 HOURS OF DAILY WEAR, TO WEAR THE SYSTEM FOR AS LONG AS YOU WISH. INTENSIVE WEAR OVER THE REQUIRED MINIMUM 10 CONSECUTIVE HOURS PER DAY AND LONGER CONSECUTIVE WEEKS OF WEAR WILL LEAD TO BETTER RESULTS.

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What is the Brava® Breast Enhancement and Shaping System?

The *Brava* Breast Enhancement and Shaping System is the only scientifically proven nonsurgical alternative for breast enlargement that exists today. The *Brava* System stimulates natural growth of the breasts without drugs, creams, or implanted materials. As a result, the breasts become enlarged and lifted by the addition of more of your own breast tissue.

The *Brava* System looks like a sports bra, but it is actually placing a gentle, sustained tension on the breasts that induces new tissue growth. The medical principle behind the System is known as tension induced tissue growth and has been used in medicine for over 30 years in other reconstructive procedures. The *Brava* System utilizes negative pressure to apply a gentle three-dimensional pull on the breasts, inducing the slow growth of your own breast tissue over the treatment period (see Figure 1).

The initial clinical study, published in the peer-reviewed scientific medical journal, Plastic and Reconstructive Surgery, showed that women who consistently wore the *Brava* System for 10 consecutive hours per day for a consecutive 10-week period grew an average of 100 cc in breast volume, or approximately one cup size. This true breast enlargement was the result of healthy natural breast growth and persisted more than 2 years after they stopped using the *Brava* System. A second clinical study confirmed these results.



The principle of tension-induced tissue growth is used widely by the medical profession for many procedures including tissue expansion, limb lengthening, and breast reconstruction. In the post-mastectomy breast reconstruction, surgeons insert a tissue expander (a silicone bag) under

the residual breast tissue and gradually inflate it to create an internal tension that generates the tissue necessary for the breast reconstruction. The creators of *Brava®* have taken this principle and, instead of an implanted device pushing from the inside, developed a patented process and design that applies the force non-invasively from the outside to enlarge all the soft tissues of the breast.

What is happening to your body?

The *Brava* Breast Enhancement and Shaping System is the only medical device that uses in-vivo tissue engineering for cosmetic enhancement. The *Brava* System works by placing gentle tension (three-dimensional pull) on the breasts. This process, when sustained, results in new breast tissue. This technique, known as tissue expansion has been used by the medical profession for the last 30 years.

Clinical research indicated that women who complied with the protocol experienced an increase in breast volume, which ranged from 35cc to 250cc of lasting tissue growth (use ranged from 10 to 26 weeks of wear).

In the early phase of wear, the initial increase that you will see is made up of of mostly swelling with a very small amount of true tissue growth. However, as you continue to use the *Brava* System, real tissue growth slowly begins to take place and by the end of treatment, there is a greater proportion of true tissue growth to swelling. Figure 2 describes the *Brava* growth cycle.

Figure 2. Nonsurgical Breast Tissue Growth¹



Baseline breast tissue. Breast tissue at initial resting state.



Early When activated, the Brava System draws air out of the domes and the breasts are gently drawn forward. Breasts increase due mostly to swelling. Little to no lasting tissue growth at this point. True breast growth is a slow and progressive process.



Late

Over a 10+ week process, the sustained tension generates both new lasting tissue and swelling. The breasts appear to be very large in size. Tension = Growth



Final

After completing use of the system (10+ weeks), the breast is enlarged by newly generated tissue. After discontinuing its use and once the breasts are stabilized (about 3 weeks), the remaining tissue shows the increase in breast volume.

1 Khouri RK, Schlenz, Murphy BJ Baker TJ.Nonsurgical breast enlargement using external soft-tissue expansion system. *Plast Reconstr Surg.* 2000;105:250-2514.

Each day you wear *Brava*[®] for at least 10 hours you will notice that your breasts become swollen and enlarged. When you remove the System the swelling subsides and your breast volume decreases. In fact, each day you put the *Brava* System on and then take it off you are going through the *Brava* growth cycle. As the weeks progress and you repeat this seesaw (on and off) process, you will slowly begin to notice that after you have had the domes off for a prolonged period of time, your breasts no longer experience a significant decrease in volume. You are now experiencing tissue growth along with the accompanying swelling (the amount of growth you are experiencing is about a droplet a day). As a rule of thumb, you know you are at the midpoint of treatment, when before putting the System on – for the next 10 hour cycle, the increase you see is the breast size you have always wanted.

The new tissue growth covers the entire breast area since *Brava* was designed to grow breast tissue in every direction. Many *Brava* users take weekly photographs of their progress to help them remember their starting point. *While this may seem unnecessary, it is a documented fact that even women who have had surgical breast augmentation forget what they looked like prior to their surgery*. These photographs, when taken in a form fitting bra or bathing suit top, help to

visualize the changes. Most *Brava* users comment that they first notice growth as they begin to fill the upper portion of their bra.

Some women report that after using *Brava*, their breasts seemed to be lifted. The gentle pull of the *Brava* System places tension on the lax skin, which directly affects the content of the breasts inducing tissue to grow. As a result, the breasts become fuller. The added fullness to the upper portion (pole) of the breast actually gives the effect of a lift to the breasts. See Figure 3.

Figure 3: Effect on breasts with mild to moderate sagging (ptosis) after using Brava



Understanding the science behind Brava®

The Brava System is based on the scientifically proven principle that our body can grow and generate new healthy tissue when subjected to a gentle and sustained tension. Tension, or some degree of stretch, is good for the cells and is the natural mechanism by which our bodies grow from infancy to adulthood as our axial skeleton accrues in length and stretches the surrounding soft tissues. This ability of the tissues to grow under the effect of tension has been extensively demonstrated and carefully studied in all types of tissues, including skin, bone, nerves, muscle, viscera, cardiovascular, and pulmonary tissue. As a matter of fact, it is well recognized that under the persistent effect of gravity, the larger, heavier breasts grow progressively downward with time. In contrast to this undesirable uni-dimensional downward pull, the Brava System applies a multi-dimensional pull that grows and fills the breasts with new tissue (see Figure 4).



Figure 4. Effects of Gravity

The Brava System causes the breast to grow in all directions. Most growth is focused in the upper portion of the breast.

large breasts to grow downward.

How do tissues grow in response to tension? The body's cells are constantly under the influence of mechanical forces. They have the ability to sense these forces and adapt to changes. When a gentle sustained pull stretches the cells, they become flattened and they respond to this tension by replicating until the perceived gap is filled and the normal equilibrium state is restored. The outcome is new tissue growth. This crucial homeostatic process encompasses several tightly integrated biochemical cascades involving growth factors, cytoskeletal components, and protein kinases.¹

When the Brava System is activated, cells in the breast are placed under tension. In response to this tension, they restore the normal balance by making new cells. During the entire treatment phase, the cells are kept under sustained gentle tension and the breasts progressively grow in size.

1 Khouri RK, Schlenz, Murphy BJ Baker T.J.Nonsurgical breast enlargement using external soft-tissue expansion system. Plast Reconstr Surg. 2000;105:250-2514.

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GROWING TRUE BREAST TISSUE REQUIRES SUSTAINED WEAR PATTERN, TIME, AND PATIENCE – THE TRUE CHALLENGE IS COMPLIANCE

It takes nearly 10 years for nature to develop and grow a woman's breasts. The *Brava®* System is a natural process; it will not outpace nature. Our research has shown that at least 10 weeks of sustained uninterrupted treatments for a minimum of 10 consecutive hours per day are required to achieve a modest one-cup size growth. This is because the cells need time to sense the need to proliferate, to respond to the growth stimulus, and to gradually deposit new tissue. In fact, the rapid visible growth when the system is first worn is almost all due to reversible swelling with little or no tissue growth. True tissue growth does not start taking place until the cells have been under constant tension-long enough for them to sense the need to restore their normal resting state and to then gear up to manufacture more tissue.

True breast growth is a slow and progressive process. It is the result of the gradual accumulation of small daily increments of newly generated tissue.

Figure 5 illustrates the expected daily growth pattern when the recommended treatment protocol of 10 hours per day of use is followed.

During the 10 consecutive hours of wear, tension induces the breast to gradually enlarge. Over the subsequent 14 hours of non-use the reversible swelling is gradually lost and a small residual amount of true tissue growth remains. The next day, the cycle is repeated and daily cycles build up upon the previous ones. With consistent wear, the result is a seesaw growth pattern as the daily process is repeated again and again. This response curve is reminiscent of the winding and unwinding of a spring and is typical of what happens with many medical treatments.

The Brava System is a medical device and the medical profession expects people to respond somewhat differently to any given medical treatment. Every Brava user will not respond in the same fashion to the same treatment dose, and different doses (amount of use) are normal and may be required to achieve the desired result. Our research indicates that we can expect three types of responses among Brava System users:

Figure 5. Daily Growth Chart



Figure 6 illustrates the daily growth curves of the A (rapid responder); B (average responder); and C (slow responder).

Figure 6. Response Chart

Women Respond Differently to Brava System



A. Rapid Responders – These are the women who notice a change immediately and who grow rapidly. These women usually had pregnancy-induced breast enlargement followed by significant volume loss after childbirth. They already have some breast volume and their breasts hang down to some extent, because the skin envelope is loose (they have some ptosis). According to the spring analogy, these women have a large and compliant spring that is a very good accumulator.

B. Average Responders – These are the women who begin noticing a change within the first few days of wear and slowly accumulate tissue growth consistent with Figure 1. At the end of the 10-week cycle, they can expect the average 100 cc growth provided they adhered to the 10 hours per day uninterrupted wear pattern.

C. Slow Responders – These are the women who, with the average recommended wear pattern, may not see a change during the first few weeks. They have tight and limited amounts of breast tissue. They are typically younger and/or are non-Caucasian and/or had no children and/or have very small breasts and/or are very thin with low body fat and/or are heavy exercise enthusiasts with high aerobic concentration. They accumulate less volume during the wear cycle and lose it more rapidly during the non-wear time. Pursuing the spring analogy, they have a small and stiff spring that is a poor accumulator. They end up unable to build upon the previous day of wear, and despite repeated daily cycles, their growth curve fails to take off from the baseline volume to grow tissue. These women require a larger dose to achieve a response. Therefore, it is recommended that Slow Responders may want to use the device longer than 10 hours per day, and for additional weeks or cycles of wear to achieve lasting growth.

While we recommend a minimum of 10 consecutive hours a day of wear, the effect of varying the intensity of wear is depicted in Figure 7a for an average responder. If the *Brava*[®] System is worn for only 7 hours per day (curve #3), there is less daily volume growth and more time to lose that growth during the rest of the day. This sub-therapeutic wear pattern is unable to build upon successive cycles and, as a result, there is no breast tissue growth. The spring is completely unwound every day and the required day-after-day accumulation fails to occur. On the other hand, with 14 hours per day of wear (curve #1), the same average responder will grow very rapidly. Therefore , it is **recommended that the Brava System be worn as intensely (10+ hours per day) as possible**, especially for those Slow Responders (younger women who had no children and have very small breasts and those body types mentioned above).

Figure 7a. Average Responder – Normal Growth

Figure 7b. Average Responder – Average Growth



The *Brava* System induces tissue growth only when it is allowed to apply continuous and persistent tissue tension over prolonged periods. As important as the daily cycle of adequate use followed by non-use periods, the progress loss incurred by missing an entire day of use is substantial.

Figure 7b illustrates the loss of progression that is experienced when the *Brava* System user misses a whole day of treatment.

By missing Day 6, for example, the volume loss continues until the system is used again on Day 7. As the growth curve reveals, missing treatment Day 6 brings back the volume growth to a Day 2 level. Missing that single day of treatment interrupts the required daily accumulation and sets back the growth chart by 4 days.

Failure to use the System for at least 10 hours over two consecutive days requires 2 weeks of additional compensatory wear time. In addition, failure to use the system for any 3 days over a 2-week period will also require 2 weeks of compensatory wear time.

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How is the *Brava*[®] System used and what results should you expect?

The *Brava* System requires from the user the commitment and perseverance to consistently wear the device for a minimum of 10 consecutive hours every day for a minimum of 10 consecutive weeks. While the average volume gained for every 10 weeks is around 100cc, individual responses varied in our experience depending upon body build and intensity of wear. Every woman, however, who used the System as prescribed was rewarded with an improvement in breast size and shape that was her very own natural tissue growth. Inconsistent wear pattern, by the same token, led to disappointing results. The *Brava* System requires commitment, dedication, and, most of all, persistence. Because of this, it is not for everybody. The major issue is the inability to wear it for at least 10 consecutive hours a day every day because it may interfere with one's social life and commitments. **In our experience, most women had to wear the System for 12 to 16 weeks to receive a 10-week effective therapeutic dose.**



Before





In women who have mild to moderate ptosis (droopiness of the breasts), the *Brava®* System provides a significant amount of breast lift in addition to breast enlargement. This is because the ptotic breasts have an already stretched out skin envelope in relation to the tighter retracted contents. The pull of the *Brava* System goes through the lax skin to directly affect the contents, inducing them to grow. As a result, the breasts become fuller, firmer, and lifted (see Figure 8).





Overview of the Brava Sport System Components

The Brava Sport is sold as a kit and contains the following components:

Domes – each consisting of a semi-rigid shell with a tacky silicone sole (base). The *Brava* Sport comes with one pair of domes. Larger domes may be necessary in the future, depending on growth level.

One SportBox[™] – self-regulating microprocessor powered by two AAA alkaline batteries.

One T-Connector tubing

One support bra and tote bag-used for washing bra

Filters – (10 filters per pack) SportBox[™] cleaning kit – cleaning tray and syringe

Instruction material - in written format

Storage container

Each element of the *Brava®* System plays a critical role in the proper functioning of the product and ultimately in the results you will experience.

Please familiarize yourself thoroughly with each component to get an understanding of its role in the System.

Domes

The semi-rigid domes of the *Brava* System have a tacky silicone sole. The domes will adhere to the body, creating a seal, when they are placed against your skin and the vacuum is achieved by *SportBox* (see Figure 9).

Due to the differences in body shapes, each user's starting dome size will be determined based on certain measurements. Once your dome size is determined, you will receive one (1) pair when you order the *Brava* Sport.

As your breasts grow, you may outgrow this initial pair and therefore move to the next larger (deeper) set of domes. Your nipples should never touch the inside of the domes when the System is activated or the System



Figure 9. Domes

will not function properly. (Call Brava Customer Care to purchase the next larger dome size).

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Figure 10. Dome Port

There is a right and a left side to each pair of domes. They give the appearance of natural contours and shapes, enabling you to wear the device at any time, while awake or asleep (most women prefer to wear it in the evening).

A small port at the lower portion of each dome is connected to the SportBox[™] with the T-Connector tubing (see Figure 10). (Do not cut tubing on initial use, see page 22).

SportBox[™]

The SportBox (see Figure 11) consists of a microprocessor, sensor, and miniature pump. This component creates and regulates the gentle pull or vacuum pressure (15-33mmHg) within your domes.

The SportBox has two power switches. The top switch turns the SportBox on and off, activating the sensor and pump. The second switch, located at the bottom, turns the alarm on and off. The alarm alerts the user when the integrity of the vacuum seal is broken and the System cannot work properly. The alarm is manually enabled at the discretion of the user and is generally utilized when the System is worn to bed. After 10 minutes without a seal, the alarm will sound for one minute repeatedly alerting the wearer of lost pressure. The alarming sound will shut off after one minute and if not addressed, will automatically shut off the SportBox.

The SportBox also has a vacuum port, centered at the top, to be connected to the domes via

T-Connector tubing; an exhaust port, located at the rear top, enables the air to escape from the pump; and a battery compartment in the back of the housing.

The SportBox has a built-in sensor that reads the vacuum in the domes every 2.3 seconds. When the vacuum drops below 15mmHg (millimeter of mercury), the pump will automatically start. The pump stops when the vacuum reaches 33mmHg. The vacuum levels cannot be changed manually.

The SportBox is powered by two alkaline AAA batteries.



Figure 11. SportBox

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T-Connector Tubing

For the SportBox[™] to create an airtight environment within the domes, a system of thin tubing is used to connect it to the domes (see Figure 12a). The tubing is connected to each dome, in-line filter and the SportBox vacuum port.





Figure 12a. T-Connector Tubing

Figure 12b. Tubing and filter

Note: The connections must be airtight in order for the System to work correctly. As illustrated in Figures 12a and 12b, the tubing should be connected to the filter which is then connected to the *SportBox* port. Excessive force should not be used when tightening the filter or the port may crack.

Support Bra

The outer support garment is designed to hold the System in place and resembles a sports bra (see Figure 13). It has been designed specifically for the *Brava* System, and it comes with a washable drawstring tote bag for easy laundering. The bra's back straps are lined with Velcro[™] and may be adjusted for a more comfortable fit. The bra also has a Velcro-lined inside pocket where the SportBox is held in place.



Figure 13. Support Bra

Note: If bra is pressing too tightly on domes, this may cause painful pressure to the ribs and sternum area. If you experience this pressure, loosen the bra.

Filters

Each *Brava*[®] System comes complete with one package of 10 filters. These filters, when used as directed, protect your *SportBox*[™] from the effects of perspiration that can clog and inhibit the proper functioning of your System. We recommend rotating the use of the filters daily and alternating them weekly (*Note: label 7 filters with a different day of the week for better tracking*). Filters can also be cleaned or additional filters may be ordered, within the U.S., by calling *Brava* Customer Care.



To attach the filter, take the threaded port (male end) located on one end of the filter and twist on to the top end (or port) of *SportBox* until secure. (Note: Do not twist too tightly.

Figure 14. Filter (SportBox with filter and tubing attached)

Excessive force can damage the port on the SportBox.) Attach the filter to one end of the tubing and the other end to the top of your *SportBox* (see *Figure 14*).

SportBox Cleaning Kit



Figure 15. Cleaning Tray and Syringe

If your SportBox is not shutting off after the domes are correctly positioned and a good vacuum has been achieved or your SportBox does not turn on, salt particles may have formed inside from perspiration buildup. Cleaning with a solution of half water and half alcohol may dislodge these particles.

Your *Brava* System comes equipped with a cleaning tray and syringe that is used to clean the SportBox (see Figure 15). However, we recommend contacting *Brava* Customer Care at 1-800-407-5304 prior to cleaning your SportBox to ensure proper operation.

(Please see section titled "SportBox wet cleaning procedure" on page 27 for further instructions on cleaning the SportBox.)

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Instructional Material

Included along with this manual and DVD are Warranty and other important information.

Storage Container

The package in which the *Brava*[®] System is shipped provides the ideal place to safely store your domes. It allows you easy access to them as well as protection from dirt and dust, keeping your System in optimum condition to ensure proper functioning. It is also the ideal place to let your domes air-dry after cleaning.

Note: The deluxe domes rack is available for purchase through Brava Customer Support.



Figure 16. Instructional Materials

Instructions for using and maintaining your *Brava* System

Precautions

- This product is designed to be comfortable to wear. If any signs of discomfort occur while you are wearing the *Brava* System, remove it and contact *Brava* Customer Care (U.S.) at 1-800-407-5304. For any medical questions, please contact your healthcare provider.
- The part of the *Brava* System that comes into contact with the skin (dome's tacky sole) is covered by hypoallergenic material that has been tested for prolonged skin contact; however, it is recommend that the *Brava* Skin Care Line be used daily for extra skin protection. Contact *Brava* Customer Care (U.S.) at 1-800-407-5304 for more details.

You should stop wearing the system if you develop symptoms of moderate to severe itching, painful swelling, skin redness, skin irritation, bone tenderness or a bruising like sensation in the sternum or rib area. Contact your health care provider for any medical questions.

 The domes are made of materials that should not be punctured, sliced, or stored at temperatures below -35 F or above 120 F. Avoid placing in a location with severe temperatures (such as a car's trunk in summer weather) as the System could become damaged. Use of the *Brava* Dome Cleanser will prolong the life of your domes.

Instructions for putting on the Brava® System

Please follow the directions carefully to achieve the best results.

Step 1.

Remove components from container box.

Please ensure that your kit contains the following items:

- 1 pair of domes. (Each dome's hypoallergenic adhesive sole is covered by a tamperresistant safety shield. Do not use the domes if the seal has been removed or broken.)
- SportBox[™]
- 2 AAA Alkaline batteries
- T-Connector tubing
- A Brava bra specially designed for the Brava System
- Tote bag (to be used for washing bra)
- Instruction guide booklet
- Cleaning and maintenance kit
- Filters
- Storage container
- (Optional STRONGLY RECOMMENDED) Brava Skin Care Kit: ordered separately

Step 2. Important points to follow before getting started

To ensure proper use and warranty coverage with your *Brava®* System, please be sure that you complete the following before using your System:

- Read the Warnings and Precautions Card (inside instruction manual packet) thoroughly.
- Complete the product registration card and mail.
- 3. If in the U.S., call 1-800-407-5304, Option 5, M-F from 9:00am to 6:00pm EST to arrange a convenient time to review the proper set up and use with your *Brava* Coach.

Step 3. Insert the 2 AAA alkaline batteries into your SportBox

Turn your system on by pressing the SportBox power button and listening for the whirl of the vacuum pump. Once you hear the vacuum pump, you can turn it off by pressing the power button a second time.

(NOTE: BATTERIES TYPICALLY LAST APPROXIMATELY 2 WEEKS AND MAY BE REPLACED AS NECESSARY)

Step 4. Prep Skin

Each day just prior to putting the domes on, clean your breasts and the underarm area with the *Brava*® Skin Cleanser and water, rinse thoroughly and dry the chest area completely. This important step will remove the layers of dead skin cells from the area where the dome makes contact with your skin. It is important to also cleanse the underarm area to remove any deodorant, powder or moisturizer that can come in contact with the dome's tacky surface. Apply the No-Sting[™] Skin Prep to the area where domes come in contact with the skin and allow this area to dry thoroughly (8 to 10 minutes) before placement of domes (If using hair conditioner in shower, be sure to wash chest area with *Brava* Skin Cleanser to remove residue). It is also very important to clean the domes every day after use. We suggest using the *Brava* Dome Cleanser for best results. The *Brava* Dome Cleanser eliminates the chance of bacteria buildup and restores the tacky surface. After cleaning rinse thoroughly (4 to 5 times), shake to remove excess water and allow domes to air-dry each day using the racks which house the domes*.

In addition to proper hygiene, it is recommended that you use the other Skin Care products that cleanse, protect and moisturize your skin while using the *Brava* System. Good hygiene and use of the *Brava* Skin Care products has been tested and proven to minimize the chance of skin irritation.

Step 5. Connect filter to top of SportBox

Gently connect filter (threaded side down) to the port located on the top of SportBox. Over tightening of filter to SportBox may result in damage to the connected filter and SportBox. Set aside the connected filter and SportBox for later connection completion.

Step 6. Put bra on

Put the *Brava* support bra on and zip completely over bare chest. Disconnect shoulder straps. Lower zipped bra to waist area.

Step 7. Remove the protective seal on the domes

<u>Remove the plastic tamper resistant sheet on the bottom of the domes</u>. The domes are marked with an "R" for right and an "L" for left. Prior to wear, be sure that the adhesive sole is

* See "Caring for your skin and domes".

clean and free of any foreign material. You can check for proper placement by making sure that the dome ports, at the bottom of the domes, face inward.

If your height is greater than 5' 7" tall, place the lowest edge of the domes at 1-3/4" inches from breast crease, this will allow proper airflow around the breast and an optimal fit over the rib cage.

Step 8. Placement of domes

The domes should be placed on your body one at a time (please refer to Diagram 1).

Hold the sides of the soft rim between your thumb and fingers. Gently rotate the dome's soft gel rim away from your body by turning your thumbs away from you. Ensure that all of your breast



Figure 17. Outward Dome Rim

tissue is completely inside of each dome by leaning forward (See Figure 17). Leaning forward allows gravity to assist with the proper placement of your breast inside the dome. In most cases, the breast crease is approximately 1-1/2" from the lowest edge of the dome's gel rim. Repeat this process with the other dome. The tacky surface on each dome's sole will assist in holding the domes on the chest until you finish putting the System on. Place the palm of your hand on the top of the dome to offer support until the bra is zipped. You will also need to use one forearm to hold first dome in place while applying the second dome to maintain a flared gel rim.

Step 9. Ensuring proper placement of domes.

Once each dome is in place, inspect the area where the dome meets the skin to ensure that the dome sits comfortably on your body and that it is properly aligned under the inframmamary crease. Make sure that there are no skin folds under the adhesive sole as these folds will act as air channels and prevent the formation of a good seal (See Diagram 1).

Any gaps at the sides of domes will be addressed in a later step.



Diagram 1. Fitting the Domes

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Step10. Attach tubing to domes

Connect the end of each tube to the port located on the lower section of the dome, ensuring a tight fit. Even though the tubing appears to be too long, <u>do not trim</u>. Only trim frayed or stretched ends of the tubing as you use the System to help ensure a tight fit on each dome port.



Picture 1. Domes On

Two semi-rigid plastic domes with specially engineered silicone gel rims are placed over the breasts.



Picture 2. Placement of

SportBox[™]



Picture 3. System On

The Brava® System is held in place with a sports bra.

Step 11. Application of bra over domes + tubing (Do not connect SportBox yet)

Once you are satisfied that the domes are positioned correctly raise the "zipped" bra over domes + tubing. Reconnect the shoulder straps with Velcro. Your bra is now in place and the vertical portion of the T-tubing will be hanging below the bottom of the bra.

Step 12. Activate the SportBox

Turn the SportBox on by pressing the power button, then, press the alarm button. You will hear a beep when the SportBox is turned on or when the alarm is activated. Both switches are toggle switches which turn on and off by the same pressing motion. Thus, make sure that you hear the beep when you turn either the system or the alarm on. See page 34 for more information on alarm use.

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Step 13. Connect system

Connect T-tubing that is hanging down from the bra to the filter already attached to the top of the SportBox (twist gently to ensure connection).

Place palm of hand on front of corresponding dome and press domes to chest until SportBox pump shuts off indicating a seal has been achieved. By maintaining this manual pressure on the domes, any gaps at side of domes or other potential air leaks are closed off until the pump generates enough vacuum pressure to secure the domes.

It is important to remain in a still and standing position while doing this so that progress toward achieving seal is not interrupted.

The seal is normally achieves in 2-10 minutes. However, the deeper domes may require the slightly longer than 10 minutes. If this occurs, alarm will begin to beep repeatedly. To stop the beeping, press both the Alarm and Power buttons twice each...once to turn Power and Alarm off and once to turn them back on. Return to pressing domes toward chest until SportBox pump turns off indicating that seal is achieved.

Once this initial seal has been achieved and the pump shuts off, it is normal for the pump to reactivate from 1 to 4 times to regulate pressure as needed. The pump will automatically shut off in less than 2 minutes once correct pressure has been regained. This requires no action on your part.

If you are still unable to get the initial seal, refer to the Frequently Asked Questions section "What to do if the pump on my SportBox does not turn off"

Step 14. Wearing the System

If the nipple is touching the dome once the vacuum has been created, you should check that your dome is properly aligned under the inframammary crease. If the alignment is correct but your nipple continues to touch the dome, you should discontinue use and contact Brava Coach or Customer Care to confirm dome size and/or order deeper domes.

During sleep, if the pump has been vibrating for more than 10 minutes, the alarm (continuous beeping) will alert you that the seal has been lost, providing that the alarm was activated. In most cases, by gently pressing the domes toward your chest, a seal can be achieved and the System begins to restore the correct vacuum pressure.

NOTE: It is important that you DO NOT press on domes once the seal has been achieved to avoid potential damage to SportBox.

To allow skin to acclimate to the domes, it is recommended that you only wear the system for 8 hours for the first 2 days. If no adverse reactions, you may begin wearing 10 hours per day for next 12 days. At this point, you may wear as many hours per day as you like. Additional hours and weeks of wear will enhance your results.

Caring for your skin and domes

After removing the System each day, clean the skin around your breasts with the *Brava* Skin Cleanser. The *Brava* Skin Cleanser is extremely gentle and will help to care for your skin during treatment.

The domes should be washed after each daily wear session, with the *Brava* Dome Cleanser which has been especially formulated to clean your domes restore the tacky surface, and extend the life of your domes. Use of the *Brava* Dome Cleanser will ensure a longer lasting set of domes. Simply spray on entire dome, wait 5 to 15 minutes and rinse thoroughly with lukewarm water. *Note:* Do not allow Dome Cleanser to remain on domes longer than 15 minutes.

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Figure 18. Wash Domes

Allow to dry, away from dust or pet hair. You can also use IVORY Bar Soap made into a lather or baby shampoo. DO NOT USE LIQUID SOAPS THAT CONTAIN ANTIBACTERIAL ADDITIVES OR ALCOHOL PRODUCT. However, please note that these do not replace the antiseptic function of te dome Antiseptic Cleanser.

Be particularly careful as you use your fingertips to gently wash the adhesive soles of each dome and do not allow a washcloth or any paper product to come in contact with the tacky sole of the domes (see Figure 18).

Note: Never scrub the domes when cleaning. This will damage the adhesive sole and render the device inoperable.

After use, clean your skin, apply *Brava* Body Lotion to your chest area. This will soothe your skin and help to reduce any irritation. Wash all lotion off prior to reapplication of your domes.

Caring for your SportBox[™]

After each daily use, remove the filter from Sport Box and disconnect filter from T-tubing (be sure not to discard the screw connector on bottom of T-tubing for filter connection).

Remove the rubber port cover (with 3 tiny pinholes) from the top of the Sport Box and turn the Sport Box upside down and place it in an EMPTY cleaning tray, with the Pink POWER and ALARM buttons facing the word Brava on the cleaning tray. (Sport Box will not fit in any other position.)

The rubber port cover can be placed on the small post at the **right** side of the cleaning tray for safe keeping until the process is complete. Allow the Sport Box to remain on the tray all day until its next use. (See Filter Use on next page)

If your Sport Box fails to start or fails to turn off, first try inserting 2 new batteries. If this fails, contact your Brava Customer Care (U.S. 1-800-407-5304 Select Option 2) to be instructed on how to WET Clean your Sport Box (see page 27).

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Filter replacement and cleaning

Using the in-line filter can help maintain the proper functioning of your SportBox. Inside your System is a package of filters, a small clear plastic disk with two attachment ports at either end. By using the in-line filter you will only need to use the "Wet Cleaning Procedure" in case of product failure.

Replace filters: To attach the filter to your System follow these simple steps:

- Take the male end (threaded port) and attach it by gently twisting it on to the port on the SportBox. (Over-tightening can damage the exhaust port on the SportBox.)
- Take the bottom end of the T-Tubing with the connector and twist it into the top end or female end (smooth port) of the filter until it is secure.



Figure 19. SportBox with filter attached

Filter Use

For best results, we recommend that filters be rotated daily to allow sufficient drying time. We suggest labeling each filter with the day of the week (Mon-Sun) to help remember which filter to use each day. Rotate them weekly. If you perspire more than average or wear more than 10 hours in one session, you may need to clean or change the filters more often. In time the filter will clog with perspiration and other particles. When the filter is clogged, the SportBox[™] sensor will assume that the appropriate vacuum level has been reached, when in fact it has not. If this occurs, the vacuum inside the domes will not be effective. Correct this by changing or cleaning the filter.

To determine whether the filter is clogged, connect the filter to the SportBox and turn the SportBox on. If the pump does not turn on, detach the filter from the SportBox while on; If once the filter is removed the pump turns on, this indicates that the filter is clogged and either needs to be cleaned or replaced.

Cleaning your filter

To clean the filter, attach a "dry" syringe to the male side of a dry filter and depress. This will force air through the filter and remove any trapped particles. *Note:* DO NOT use any liquid for this cleaning procedure.

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Dry Clean Process for SportBox (Daily process)

It is necessary to do a **DRY CLEAN PROCESS** (same as WET Clean but without alcohol/ water mixture) after *every* use for optimal care. It is important to allow the pump to run (vibrate) at least 10-20 minutes daily for optimal maintenance. In extreme cases of perspiration, you may allow the pump to vibrate up to an hour daily with extended hours of wear. This is to avoid moisture buildup within the Sport Box which may cause potential malfunctioning or damage.

PROCESS:

- Remove the filter from top of Sport Box.
- Carefully remove the small gray port cover on top of Sport Box (looped over white vacuum port with 3 tiny holes).
- Hang port cover on the small peg at right side of cleaning tray (with Brava logo facing you for proper aligment and also as a reminder to replace port cover when process is complete).
- Turn Sport Box Power ON (audible Beep) and Alarm OFF (Silent/No Beep) to allow pump to run indefinitely, not just 10 minutes.
- Turn Sport Box upside down with pink buttons facing Brava logo on tray and place inside the DRY tray until desired time is reached. Note: Box will only fit in cleaning tray if properly aligned. (Severe cases of moisture buildup may require longer drying process.)
- When process is complete, replace rubber port cover carefully over white vacuum port.
- It is recommended to change batteries every 7-10 days to avoid loss of power during a wear session or while sleeping, causing loss of your daily therapy session requiring make up time.

Please Note: See Instructions for *Wet Cleaning Process* and consult with a Customer Care Representative before performing this process.

Also Note: PRIOR to each Wet Clean Process, perform a 1-2 hours Dry Clean Process, the follow up again with a 3-5 hours Dry Clean Process after Wet Cleaning. Insert new batteries in Sport Box prior to next wear session.

SportBox Wet Cleaning Procedure

The SportBox wet cleaning procedure should be used only if you encounter a problem with your SportBox. <u>Please contact Brava Customer Care before</u> <u>attempting this procedure</u>. Prior to starting the wet cleaning process, place the SportBox upside down in a <u>dry cleaning tray</u>. While upside down, turn on the SportBox for 2 hours. When complete, proceed to the wet cleaning process. After wet cleaning follow with a 3 - 5 hour dry cleaning cycle before the next wear session.



Figure 20. Cleaning Tray and Syringe Add 1cc of alcohol



Figure 21. Cleaning Kit Add 1cc of tap water

Port cover storage post

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WARNING – NEVER TURN YOUR SPORTBOX UPRIGHT UNTIL THE DRYING CYCLE IS COMPLETE. IF TURNED UPRIGHT WHILE STILL CYCLING, ANY MOISTURE INSIDE THE SPORTBOX CAN CAUSE SERIOUS DAMAGE TO THE MOTOR. CONTACT BRAVA® CUSTOMER CARE AT (U.S.) 1-800-407-5304 FOR FURTHER INSTRUCTIONS.

Using the included cleaning tray and syringe, follow these steps (*Remember to do a 2 hour dry cleaning prior to the wet cleaning process*).

- Remove the syringe and cleaning tray from your container box. Fill the syringe to 1cc with isopropyl alcohol (rubbing alcohol). Empty the syringe into the side of the cleaning tray marked "Fill to line" (See Figure 20). Then fill the syringe with an additional 1cc of cool tap water. Empty the syringe into the side of the cleaning tray marked "Fill to line". You will have 2cc of the 50/50 mixture of alcohol and water in the same cleaning tray. (same reservoir).
- 2. Remove any filter or tubing attached to the SportBox[™]. (NOTE: Do not discard the filter or tubing as you will need this after the process is complete.)
- 3. Locate the rubber port cover on top of the SportBox. This cover loops over the vacuum port (small tube) at the top of the SportBox and covers the exhaust port opening. Remove the rubber port cover by gently lifting it upward and pull it off completely. Now, place the rubber port cover on the cleaning tray post for easy storage during this process (see Figure 21). (NOTE: Do not discard the port cover as you will need this after the process is complete.)
- 4. Turn both the SportBox and alarm on (listen for audible "beep" to indicate ON).
- **5.** Turn the SportBox upside down, with the vacuum port facing down, and place it into the cleaning tray on the side with the solution. (To be sure you have it on the correct side, the guidepost will only allow you to insert the SportBox in the correct position for cleaning) (see Figure 21).
- 6. Allow the SportBox to run until the alarm sounds (approximately 10 minutes). During this time, the alcohol and water mix is being cycled through the SportBox's pump, removing any debris and salt crystals left in the pump from use. You will see the fluid empty into the other reservoir of the cleaning tray.
- 7. Once the alarm sounds, after about 10 minutes, the wet cleaning process is complete. Turn the SportBox on again. <u>While the SportBox is on, be sure to keep the SportBox in the inverted (upside) down position</u>. With your other hand, empty the cleaning tray of all fluid and replace the inverted SportBox onto the empty cleaning tray. Turn "OFF" the alarm, to allow the Sport Box to do a dry cycle for 3-5 hours after the "wet clean" cycle, for best results before your next wear session. Remove the SportBox from the cleaning tray, shake the SportBox gently while inverted to remove excess fluid and dry the port with a soft paper tissue. Don't forget to replace the rubber port cover after cycling is complete. Once you finished this process, you should change batteries to ensure the proper amount of power for the next wear session.

NOTE: After the cleaning process you may notice a slight difference in the pump's sound (i.e., slightly louder). The normal sound should resume within a few hours. After long drying cycles, batteries should be changed to ensure proper functioning.

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Emergency Cleaning Procedure

To be used <u>only</u> with the assistance of *Brava®* Customer Care or if SportBox does not turn on.

In some instances, even when you have followed the wet cleaning procedure, the SportBox may not function properly. This can happen when debris (usually made up of salt crystals from perspiration) is trapped in the SportBox's check-valves. In order to release the debris, the system must be manually flushed with the assistance of the syringe. When using the syringe, follow these steps:

WARNING – NEVER TURN YOUR SPORTBOX UPRIGHT WHEN WET CLEANING. IF TURNED UPRIGHT LIQUID CAN ENTER THE SPORTBOX AND WILL RESULT IN SERIOUS DAMAGE. CONTACT BRAVA® CUSTOMER CARE

- 1. Remove the syringe from the cleaning kit.
- 2. Fill the cap of the isopropyl alcohol bottle with only alcohol.
- 3. Take the syringe and fill it with 3cc of the isopropyl alcohol.
- **4.** Remove rubber port cover from the SportBox. Turn the SportBox on. Initially, you will hear a single beep. Later, you will hear the pump activate.
- Hold the SportBox in the inverted or upside down position during this emergency cleaning procedure. (You should hold the SportBox over a sink so that the alcohol can empty safely.)
- **6.** Gently twist the end of the syringe into the vacuum port (small tube located at the top of the SportBox) and empty syringe into port.
- 7. Turn the alarm off and place in empty cleaning tray to cycle and dry for 3 5 hours prior to use. The Sport Box should activate eventually, if not immediately, while drying. If not, contact Customer Service for assistance.
- 8. Replace rubber port cover and store SportBox.

Helpful tips and frequently asked questions (FAQs)

Listed below are helpful tips and FAQs to ensure that you get the full benefit from wearing the System. Please familiarize yourself with this section.

Tips:

- Avoid placing the Brava System (including the domes) in extreme heat or extreme cold temperatures.
- Never dry any components in direct sunlight.
- Never place any of the *Brava* System components, except the bra, in any automated washing or drying devices (e.g., washing machines, dishwashers, microwave ovens, electric dryers, etc.).
- Never leave the Brava System in your car. Extreme heat or cold will damage it.
- Keep all components out of reach of children. Improper use could result in suffocation.
- Keep all components away from pets. (One of the most common reasons for the domes to lose their tacky surface is coming in contact with pet hair.) Please keep the *Brava* System domes covered in their protective storage.
- Use only AAA alkaline batteries. For optimum performance, use same brand of batteries and change both batteries at the same time.
- Discontinue use if you experience any skin changes, such as a significant rash or skin blistering. If any changes occur, call your physician immediately.
- Do not wear the Brava[®] System during any type of exercise activity (e.g., swimming, running, lifting weights, etc.).
- Never shower with the SportBox.
- The Brava System cannot be shared for reasons of hygiene.

Note: To ensure proper dome adhesion and to avoid skin irritation, before placement of domes, be sure:

1. Your chest area is completely dry.

2. The No-Sting Akin Prep wipes have been applied and skin area is completely dry (8 to 10 minutes).

FAQs:

Do I need to power the SportBox before I wear the System for the first time?

Yes. Just insert two AAA alkaline batteries in the rear of the SportBox to power it.

What kind of Batteries does the Brava Sport use?

AAA alkaline batteries ONLY. For optimum performance, use the same brand of batteries and replace both batteries at the same time.

How long will the batteries last?

It is best to change the batteries every 7 to 10 days to mantain optimum therapeutic treatment.

How can I best care for my skin when using the Brava System?

Proper cleaning of your System's domes and personal hygiene are essential when you wear the *Brava* System. Each day before putting the domes on, gently clean your breasts and the surrounding area with the *Brava* Skin Cleanser (Baby Shampoo or Ivory Bar Soap lather) and water, rinse well and dry the chest area completely. This important step will remove the layers of dead skin cells from the area where the dome makes contact with your skin. Apply the No-Sting[™] Skin Prep to the area where domes come in contact with your skin. Allow 8 to 10 minutes (or as long as necessary) to dry before placement of domes.

After removing the System, clean the dome's tacky surface with the *Brava* Dome Cleanser. This helps to remove the dead cells and regenerate the dome's tacky surface. Apply a small amount of *Brava* Skin Lotion to soothe and nourish the skin after you wash chest area or shower using your normal bath soap.

If I notice that my domes are losing their tackiness or stickiness, what can I do?

Be sure to clean the tacky surface on each dome <u>daily</u> after use with the *Brava* Dome Cleanser (or Baby Shampoo or Ivory Bar Soap lather). Usually the dome's seal can be greatly improved by simple cleaning. Spray on, leave for 5 to 15 minutes*, then place the dome in the sink to rinse thoroughly and shake excess water off. Domes should be air-dried by placing them upright. *Brava* dome racks can be purchased by calling *Brava* Customer Care.

Next, clean each side of your chest area where the domes will be placed and also your underarm area. You can wash your chest area with soap and a washcloth. This will remove any dead skin cells and allow for a better seal. Dry this area completely prior to repositioning each dome. A good seal is important to achieving true tissue growth. A decrease in tackiness can cause you to loose pressure inside the domes. Daily cleaning removes dirt and grime and helps to restore the tacky surface to the soles of your domes.

* (not more than 15 minutes)

Do not use moisturizer, powder or deodorant when you are wearing the System. Never use paper products or towels to dry the domes as lint or paper may adhere to the tacky surface. Never dry domes in direct sunlight. Never use harsh chemicals on the dome's tacky surface. Never use any product that contains any antibacterial product or moisturizing product to clean the domes. When drying, keep domes in the stackable cardboard racks inside the storage container. This will keep dust and pet hair from sticking to the surface.

What can I do if I cannot get a proper seal with each dome?

First, check to see that all connection ports are well secured. (Domes to T-tubing, T-tubing to filter screw cap, Filter to Sport Box and Domes snug to the skin)

- 1. If there are any gaps between the skin and the domes tacky rim, apply gentle but consistent pressure with the palms of your hands, pressing the domes snuggly to your chest. Maintain this pressure to eliminate air entering around the circumference of the domes until the seal is fully achieved and the Sport Box pump sound has stopped. Due to anatomical differences, you may find the need to vary the position of your domes to customize the fit to your ribs and chest. See Figures 22a and 22b below for some suggestions that may be helpful.
- 2. If your chest area is slightly damp or the No Sting Skin Wipe is not sufficiently dry, you will not be able to achieve optimal pressure or get a seal. To correct this, remove the domes and wash your complete chest area again with Brava Skin Cleanser, rinse well and dry thoroughly. Then re-apply one **No Sting Skin Prep** (only one per wear session). Allow No Sting Skin Prep to dry completely before re-applying domes (8 to 10 minutes).

Figure 22a: Inward Facing





- Place domes snugly together. Secure domes to chest with the adhesive area of the dome.
- Do NOT allow domes to overlap in the middle as this will cause air to escape and lose vacuum seal. This may also cause added pressure to sternum causing pain between your breasts.

- Try to incorporate all the breast tissue INSIDE the domes, rather than allowing the adhesive of the domes to rest on your actual breast tissue. <u>Growth only takes place on the tissue</u> <u>INSIDE</u> the open space, not under the gel portion of the domes.
- Remember to flare out the gel portion of the domes ALL the way around the domes. By
 doing this, it prevents the soft gel rim from folding under or inside the rigid portion of the
 domes when the SportBox[™] is activated. Do not place the tacky surface on the soft tissue
 of your breast, it should be placed outside the breast tissue area. If you accidentally position
 soft breast tissue on the dome's tacky rim, the tissue will be placed under tension as the
 breast are drawn forward. The soft breast tissue, when attached to the dome's rim, will
 adhere and place unnecessary friction on the skin area that can become painful and
 irritated if not corrected. If the gel rim is allowed to roll under, you will lose your seal more
 quickly and over time this will damage the domes.
- 3. If you are still unable to obtain a good seal, the tacky sole may need to be cleaned. Please review cleaning instructions on page 24.
- 4. Check to see that domes are not damaged. Any open area between your skin and the soft gel rim can cause a leak in the system. Excessive pilling or balling on the domes tacky gel surface can also indicate damaged domes. However, <u>some pilling or balling is normal with use</u>. Breakdown of the tacky surface can inhibit achieving a good seal. In this case, you will need to order a new set of domes. Be sure you are cleaning your domes daily and are using the proper products (see page 24).
- 5. If you are unable to achieve a proper seal, you may have outgrown your current dome size. You may need to progress to the deeper-size domes. If your nipples touch the inside of the dome, you will need to move to the next larger dome size. As a rule, when the distance between the nipple and inside of the dome is approximately 1/2" at peak swelling (i.e., at the end of your 10 hour session while your system is on and under vacuum pressure), you should move to a larger size dome.

If the alarm on the SportBox sounds, what does this mean and what should I do?

Silence the alarm by pressing the alarm button and also turn off the SportBox. The alarming indicates the Sport Box pump has been running for 10 minutes indicating you could have lost a seal. When the seal is broken for a period of 10 minutes and the alarm is on, the alarm will automatically sound with a continuous beeping noise for 1-minute). After reseting both the POWER and ALARM button ON, gently press both domes toward your chest and maintain pressure to help remove excess air inside each dome. Be certain that all edges of the domes are smooth and not rolling inward and that each area of the domes tacky surface is properly adhered to your chest area. This process allows the SportBox to re-pressurize the domes quickly.

The alarm is activated when you hear a single beep. Pressure has been achieved when POWER button is pressed and you hear only a single Beep with no vibration.

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I do not want others to hear the alarm. If I monitor it myself, can I keep the alarm off?

Yes, you may choose to keep the alarm off. The alarm button is located on the lower right side of the SportBox. The alarm is activated when you press the ALARM button and hear a single beep. To deactivate the alarm, press the ALARM button and you hear no beep.

(Note: It is recommended to always use the alarm feature during wear to avoid lost therapeutic time. Otherwise, if the seal is lost and you are not aware of the loss in pressure, the motor will run continuously until the batteries die, providing no therapy during this time.)

What do I do if the pump in my SportBox[™] does <u>not</u> turn off?

There are a few possible solutions if the pump remains on for more than 10 minutes at a time.

- 1. Check to see if the tubing is properly connected. If loose, reconnect each tube. If the end of tubing has become frayed, trim a small amount and reconnect to dome ports.
- 2. Check to ensure that both domes are positioned securely. Press down on each dome to ensure a tight seal and maintain pressure until motor stops.
- 3. If the SportBox continues to pump for more than 10 minutes and all other checks have been completed, the SportBox may need cleaning. (Refer to Caring for your Sport Box)

To ensure proper operation of your SportBox, disconnect from the System, turn the SportBox on (you will hear the pump sound), place your index finger over the port located on top of the SportBox and press down firmly. If your SportBox turns off when the port is blocked, it is functioning properly. You should replace the filter and re-attach your System.

Using the filters will help to ensure proper operation. See the section CARING FOR YOUR SPORTBOX. <u>NEVER</u> USE THE SPORTBOX WITHOUT FILTERS. ROTATE FILTERS DAILY FOR OPTIMAL PERFORMANCE.

4. Finally, if your SportBox does not turn off, please contact *Brava®* Customer Care to assist you in further trouble shooting.

What material is the bra made of and how do I clean it?

The bra is made of 75% Nylon and 25% Spandex.

Each bra comes inside a washable tote bag. After wear, first remove the domes and the SportBox from the bra. Place the bra inside the tote bag, and launder in cold water using the gentle cycle. The bag will protect your other articles from possible damage from the Velcro[™] straps. We recommend that both bra and laundry bag be dried flat.

WARNING: Never launder the bra with the domes and SportBox attached. Laundering of domes and SportBox will cause severe damage to each.

How often should I change the filter on my SportBox?

It is recommended to alternate filters daily to allow thorough drying before the next use. If you perspire heavily when using the System, you will need to change them more often. When using for longer than 10 hours per day, filter should be changed twice during this time. (See the section on Filters on page 25).

I noticed water droplets inside the domes shortly after I put on the System. Is that normal?

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Yes, perspiration may bead up on the inside surface of the domes. This is normal and should not be a cause for alarm.

Does the room or outside temperature need to be considered before wearing the Brava® System?

Yes. You will want to wear the *Brava* System in a comfortable environment. Never wear the domes in extreme heat. If any skin discomforts occur, discontinue use and contact your physician.

Can I leave the Brava System in my car when I am not using it?

It is not advisable to leave the *Brava* System in your car or outside in direct sunlight. Any extreme heat or cold will affect the action of the System.

When I remove the Brava System I noticed my breasts are slightly red and there are red marks in the area where the domes come in contact with my skin. Is that normal?

Yes. You will notice temporary redness to the breast area, but this should disappear within 1 or 2 hours after removing the System. To care for your skin while using the *Brava* System, it is recommended that each day after removal of the System, you clean your chest area with the *Brava* Skin Cleanser, rinse thoroughly and pat the area dry. Next, apply a small amount of *Brava* Skin Lotion to soothe the area. If redness persists or if you notice any other skin changes, discontinue use immediately and contact your *Brava* Coach, *Brava* Customer Care or Physician as soon as possible.

When I have the System on, my breasts appear larger and red in color, is that normal?

Yes. When using the *Brava* System the gentle tension to the breast increases circulation. This causes some swelling, and after weeks of use, this temporary increase will slowly become true tissue growth. If any pain or open skin irritation occurs, discontinue use immediately. Typically, redness disappears within approximately 1-2 hours after removal of the System.

I noticed that my breast is touching the inside of the dome. Is that OK?

No. If you notice that the tip of your breast or nipple touches <u>anywhere</u> inside the dome, you should discontinue use immediately and move into the next deeper sized dome. When your breast tissue touches the inside of the dome, you have outgrown your domes. Using the incorrect size (i.e., too small) could result in skin changes such as blistering. If you are in need of a larger dome size, please contact *Brava* Customer Care to purchase new domes. (In the U.S., call 1-800-407-5304)

Should I experience any pain when using the Brava® System?

You should never feel pain when using the System, but remember, it will take a few days of adjustment to reach your personal comfort level. *Brava's* patented design allows for a painless experience. If you experience any type of pain when using the System, please discontinue use immediately. Please contact your *Brava* Coach, *Brava* Authorized Physician or *Brava* Customer Care Representative as soon as possible.

If pressure is felt at the mid-line area, unzipping the bra approximately 1/2 of the way down (you may secure it with a safety pin) will reduce the pressure. If pressure persists, discontinue use and contact your *Brava* Coach or *Brava* Authorized Physician.

Do you have any suggestions on how to get a good night's sleep if I decide to wear Brava to sleep?

When you sleep in the *Brava* System you will need to sleep on your back. To help get into a comfortable position, we recommend the following pillow arrangement:

- 1 pillow under your head to support your neck (horizontal)
- 2 pillows, one under each arm (in the vertical position to support between your elbows and armpit areas)
- 2 pillows, one under each knee area pulled closely to your buttocks to relieve lower back stress.

This places you in a semi-reclined position and removes pressure from any one point, adds support and reduces the need to sleep on your side. Keep your room cool as you are now wearing more clothing than you are used to.

What clothing can I wear when I have the System on?

Loose fitting clothes such as a large denim shirt or a man's size oxford shirt seem to camouflage the System best. You can also wear a large blousy shirt or a large sweatshirt.

When I take the System off, my breasts are swollen and my nipples are sensitive. Is this normal?

Yes. Your body is working hard to grow more breast tissue and increases the amount of blood circulating in that area. Your breasts become enlarged and may be sensitive. We recommend using a bra in a larger size without a seam. Many women prefer a molded seamless cup bra as the seams can cause irritation.

NOTE: After use, wear loose clothing. It is best to wear lingerie and clothing that does not constrict the breasts after wearing the System. Your breasts are swollen and loose fitting clothing helps to keep the tissue swollen for a longer period of time and helps to encourage growth. You may wear a "lift bra" but avoid "flattening" the breast tissue.

If you are planning on wearing low cut apparel after using the System, be sure to allow at least 1 hour for the redness to dissipate. Using the *Brava* Body Lotion after removing the System helps to reduce redness.

Can I use the Brava System if I am taking hormones?

Yes. You can use the System while taking birth control pills or while on hormone therapy.

Is there any way for me to track my results?

A great way to help you track your progress, is to use a formed or molded bra in a size larger than you usually wear (AA cup would get a molded A bra) and take weekly pictures of yourself in this bra from different angles (front, side, semi-oblique) at end of non-wear period (not immediately upon removal). You will notice that you will begin filling out the bra more and more as the weeks go by. Most women tell us that they notice most of the growth in the upper portion of the breasts, they start to see the cup filling up and some cleavage.

How do I know whether I had a successful night wearing Brava[®] when I was sleeping?

Having visible swelling in the morning when you first remove the System, is confirmation that you had a successful therapeutic session.

The domes seem too large for me. How do I know that I am in the correct size?

There should always be space between your breasts and the inside of the domes. Proper space is above 1/2'' to 2 1/2'' from your breast to the inside of the dome when wearing the System at the end of a 10 hour wear session and while the vacuum is on.

How long should I plan on wearing the System?

Brava should never be worn for less than 10-weeks. However, as a rule of thumb, you know you are at the midpoint of treatment, when before putting the System on, for the next 10 hour cycle, the increase you see is the breast size you have always wanted.

If I purchased the System from anyone other than a Brava® Authorized Physician, Brava, LLC or an Authorized Brava Domestic or International Distributor, will I able to get product support and service?

No. Support is only available on product purchased through *Brava*, LLC or one of the above mentioned resellers.

How will I know when I should go into the next size dome?

When the nipple is within 1/2" from touching the inside of the dome. NOTE: Even though there may be sufficient space at the apex ("nipple of the dome") of the dome, if your nipple sits low in the dome, and it is 1/2" from touching the sides of the dome, you should <u>move</u> into a larger (deeper) dome.

If I see any skin irritation or experience any discomfort at the mid-line of my chest, can I keep wearing the System?

No. You should never wear the System if your skin is irritated or experience a bruise-like sensation in the chest area or rib. Remove the System and call a Brava Coach for advice on when to re-start the System and how to avoid these issues.

Can I use any tapes or Band-Aids to cover tender areas while wearing Brava?

Never use any restrictive items such as tapes or Band-Aids anywhere where the domes make contact with the skin or on the skin inside the domes. Your breast tissue will expand during your 10 hour wear session and the bandaged area will not. This may cause blistering and thus cause set backs due to the inability to wear the System while these areas heal.

If I need product support or need additional accessory items how can I contact you?

If you need product support or need to order any accessory items, you may call 1-800-407-5304 option 2 Monday through Friday from 9:00am to 6:00pm EST or email customersupport @brava.com.

Please have your UIN (Unique Identification Number) available when you call. Your UIN number, an eight digit number, is located inside the battery compartment cover and on the outside of your SportBox packaging. This number identifies you as a registered Brava user and will help us to serve you better.

If you are just starting Brava and wish to set up your coaching appointment, please call 1-800-407-5304 option 5. Leave your name, your telephone number and the best day and time to reach you and a Brava Coach will contact you.

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FCC REQUIREMENTS

This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

