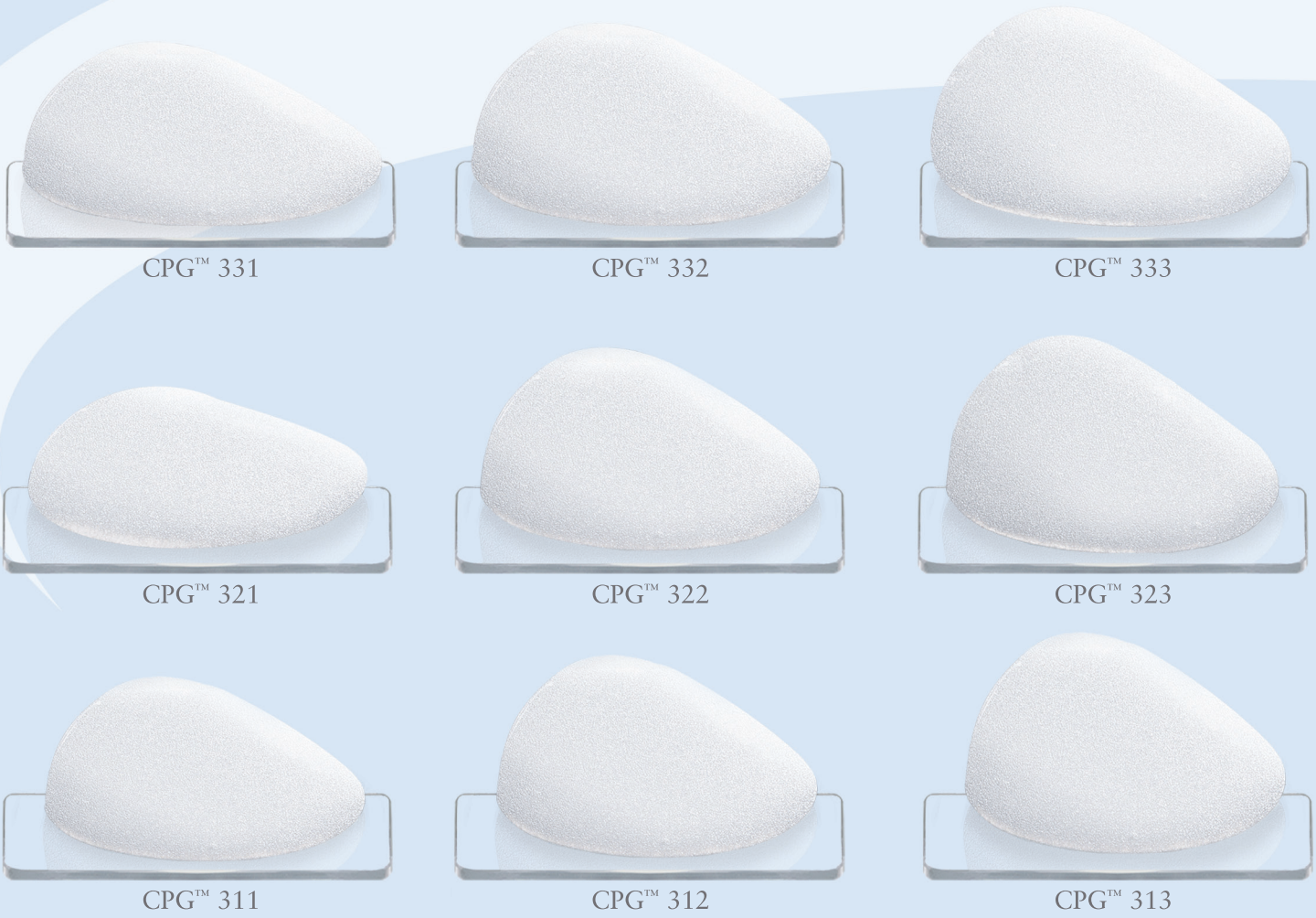
Surgical Technique Guide

Contour Profile® Gel Family – The 300 Series



CPG™ 331 CPG™ 332 CPG™ 333

CPG™ 321 CPG™ 322 CPG™ 323

CPG™ 311 CPG™ 312 CPG™ 313

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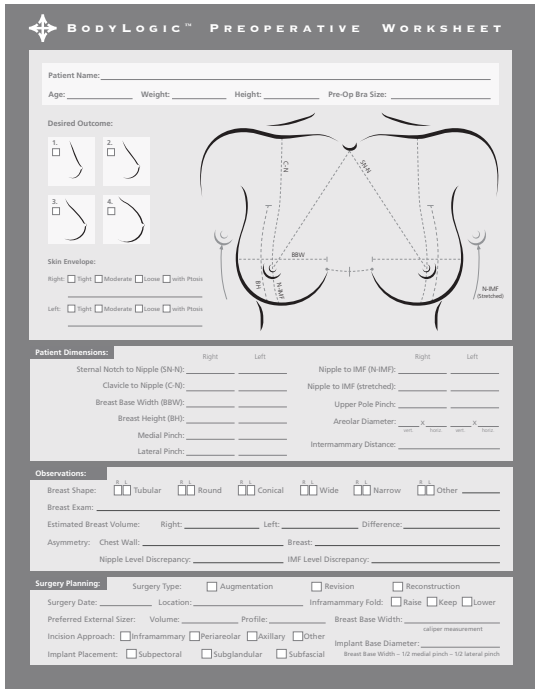
This monograph is designed to provide the surgeon using the CPG™ implant with guidance that may be useful when using the CPG™ implant. It outlines opinions from surgeons, and are not necessarily those of Mentor.


BodyLogic™ Preoperative Worksheet

Patient Name:

Age: Weight: Height: Pre-Op Bra Size:

Desired Outcome:

Skin Envelope:

Right: Tight Moderate Loose with Ptosis

Left: Tight Moderate Loose with Ptosis

Patient Dimensions:

Sternal Notch to Nipple (SN-N):
Clavicle to Nipple (C-N):
Breast Base Width (BBW):
Breast Height (BH):
Medial Pinch:
Lateral Pinch:
Nipple to IMF (N-IMF):
Nipple to IMF (stretched):
Upper Pole Pinch:
Areolar Diameter:
Intermammary Distance:

Observations:

Breast Shape: Tubular Round Conical Wide Narrow Other
Breast Exam:
Estimated Breast Volume: Right: Left: Difference:
Asymmetry: Chest Wall: Breast:
Nipple Level Discrepancy: IMF Level Discrepancy:

Surgery Planning:

Surgery Type: Augmentation Revision Reconstruction
Surgery Date: Location: Inframammary Fold: Raise Keep Lower
Preferred External Sizer: Volume: Profile: Breast Base Width:
Incision Approach: Inframammary Periareolar Axillary Other
Implant Placement: Subpectoral Subglandular Subfascial
Implant Base Diameter:

To assist you in your planning, we created the Breast Surgery Pre-Operative Planning Worksheet. This helpful worksheet can be obtained from your local Mentor sales representative.

Sample of form

Pre-operative Consultation

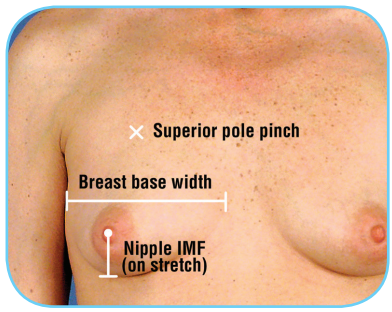
Consideration should be given to taking the following measurements during the pre-operative consultation. These measurements will allow for optimal pre-operative planning for the Contour Profile® Gel implant.

1. **Nipple to inframammary fold taken on stretch.** Allows pre-operative planning of new inframammary crease (IMC) level. (As an example, please see chart on the following page for the CPG™ 321).

2. **Breast base width.** The implant base width should be less than or equal to the breast base width measured from the para-sternal region at the pectoralis major origin to the lateral border of the breast. This will reduce the chances of implant palpability as well as other complications.

3. **Breast envelope assessment.**
   - tight – young (<25 years old), thin, nulliparous
   - normal – 30-40 years old, nulliparous or parous
   - loose – postpartum (>40 years old), skin striae

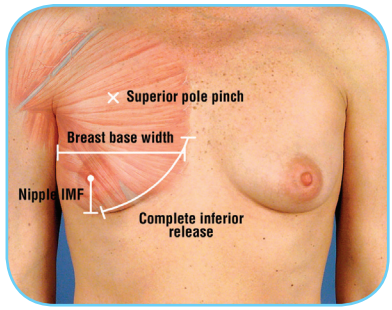
4. **Superior pole thickness (cm, measured with a caliper).** To determine the quality and amount of overlying soft tissue coverage. See "Plane of Pocket Dissection" on following page.



Surgical Technique

The key points for using the CPG™ implants include:

- Precise muscle release
- Precise pocket dissection without blunt dissection
- Minimal initial lateral dissection
- Proper implant positioning at the inframammary crease



Implant Selection

Augmentation

The width of the selected implant should be less than or equal to the breast base width for augmentation patients. The pocket dissection needs to fit the width of the selected implant.
This is the single most important technical point for Contour Profile® implant augmentation.

Reconstruction/Revision

In reconstruction and revision cases, one may need to select an implant based on the pocket size. In expander reconstruction, it is preferable to have the final expanded pocket width ≤ the desired implant width at the 2nd stage implant exchange. In the first stage of the reconstruction, it is important to select the expander size carefully, if the CPG™ implant is to be used as a follow up implant. It is recommended that the smallest expander to adequately expand the pocket be used. Subsequent widening of the pocket in the 2nd stage may be required and will allow for a precise implant-pocket fit. In any reconstruction or revision case with a pocket wider than the desired CPG™ implant, specific techniques to narrow the existing pocket are recommended.

Incision Planning

The typical three incisions (inframammary fold, periareolar, and transaxillary) can be used with the CPG™ implant. However, there has been limited experience with the transaxillary approach using the CPG™ implant; less pocket control and visibility may make the use of this incision more challenging.

Inframammary Approach

Correct placement of the inframammary incision should result in the incision lying exactly in the new inframammary fold (a length of 5 cm is generally adequate).

Plane of Pocket Dissection

Results with a subglandular vs. a subpectoral pocket plane ultimately depend on the quality, quantity and thickness of the overlying breast tissue, as well as implant soft tissue dynamics. The best assessment of adequate soft tissue, permitting placement of a subglandular implant, is superior pole pinch. In a patient whose superior pole pinch is greater than 2 cm, the subglandular pocket may be considered; the tradeoffs vs. benefits should be discussed with the patient. In a patient with a superior pole pinch less than 2 cm, subpectoral implant placement is recommended.

Pocket Dissection

Precise pocket dissection is essential for this type of implant.
Overdissection of the pocket will result in a greater potential for implant migration and rotation. The texturing of the CPG™ implant will provide more tissue contact than the standard round Siltex™ implant.

Due to the dynamics of the CPG™ implant, it is advised to dissect your pocket with cautery dissection only under direct vision. Fine-tuning of the pocket should be done with the implant in place with very gentle finger dissection.

CPG™ 321

Implant Volume	A:IMC
120 cc	3.5-4.5
135 cc	3.5-4.5
155 cc	4.0-5.0
180 cc	4.0-5.0
215 cc	4.5-5.5
245 cc	4.5-6.0
280 cc	5.0-6.5
315 cc	5.5-6.5
355 cc	6.0-6.5
395 cc	6.0-6.5
440 cc	6.5-7.0
480 cc	7.0-7.5

Areola (A) – Inframammary Crease (IMC)

Muscle Release

There is a large degree of variability in the surgeon's release of the pectoralis major. A common technique with this implant is to release the pectoralis major muscle full thickness into the subcutaneous tissue without any medial pectoralis major muscle release along the sternal border. The final details of the pectoralis release is left up to the discretion of the surgeon.

Use of Drains

In augmentation cases with a tighter breast envelope and a dry, precisely dissected pocket, a drain is not necessary. In patients with a loose breast envelope (postpartum), a drain for 48 hours may be beneficial. The ultimate use of a drain will be at the discretion of the surgeon. It is recommended that a post-operative drain be used for all reconstructive patients.

Proper Implant Positioning

The implant should be placed in its proper position prior to incision closure. Particularly in augmentation, the base of the implant should be at the level of the new inframammary fold and the orientation mark should be checked for proper implant alignment. This is particularly important in patients with tighter breast envelopes that will result in less implant settling postoperatively.

Equally important is to assure adequate redraping of the muscle/breast tissue prior to closure. Once the implant has been positioned appropriately, the skin muscle/breast skin should be redraped with the surgeon's finger. This redraping process must be repeated any time the implant position is adjusted.

Post-Operative Management

Post-operative support with a bra, binder, or both is advisable for 3-6 weeks. The surgeon's usual post-operative regimen with a shaped implant should be employed.

Important Safety Information:

MemoryGel® breast implants are indicated for breast augmentation in women at least 18 years old 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 are pregnant or nursing.

Breast implants are not lifetime devices and breast implantation is not necessarily a one-time surgery. The most common complications with the MemoryGel® breast implants include reoperation, capsular contracture, asymmetry, and breast pain. A lower risk of complication is rupture. The health consequences of a ruptured silicone gel-filled breast implant have not been fully established. Screenings such as mammography, MRI, or ultrasound are recommended after initial implant surgery to assist in detecting implant rupture.

Your patient needs to be informed and understand the risks and benefits of breast implants, and provided with an opportunity to consult with you prior to deciding on surgery.

For detailed indications, contraindications, warning and precautions associated with the use of MemoryGel® breast implants please refer to the Product Insert Data Sheet provided with each product, or review the Important Safety Information provided at www.mentorcorp.com.

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