



Preoperative & Postoperative Instructions for PFB Study

Between Laser Treatments:

- ☞ Shave only when directed to and use only the supplies that were provided:
 - Bump Fighter Razor® American Safety Razor Company
 - Bump Fighter Cartridge Refill Pack® American Safety
 - Bump Fighter Shaving Gel® American Safety Razor
 - Cetaphil Cleanser® Galderma Laboratories, Inc.

- ☞ You will need to shave for seven consecutive days prior to each treatment session.

- ☞ You will be given a shaving log at each visit to document the date and times of when you shaved.
 - Document the amount of irritation when shaving each day.
 - Use the scale provided in the log to rate your irritation.

SHAVING SCALE	
1	No irritation
2	Mild irritation
3	Moderate irritation
4	Severe irritation

- You need to bring the shaving log with you to your first appointment.

- ☞ *You will experience some mild to moderate irritation and develop a certain number of razor bumps when you shave. However, the amount of irritation is expected to decrease with each subsequent treatment.*



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- ☞ You will maintain your “No Shaving” status during all other days until you have completed six laser treatments.
- ☞ You may use clippers to maintain a hair length 1/8 of an inch).

After completing your 6th laser treatment:

- ☞ You will wait 4 days and will then begin to shave daily.
 - If you are experiencing any blistering, crusting, or pain on the 4th day, contact an investigator prior to resuming shaving for a re-evaluation.

☞ You will continue to shave daily for the next six months.

☞ If you experience a moderate or severe amount of irritation *after completing your 6th treatment:*

- Contact the assigned investigator for an evaluation.
- You will be seen within 48 hours.
- Continue to shave unless otherwise directed.
- During your evaluation, the investigator will determine whether or not you can continue in the study.

3rd and 6th Month Evaluations

You will be reevaluated on the 3rd and 6th month from the date of your 6th treatment

At the 3rd Month Postoperative Evaluation:

- ☞ You will submit your 90 day shaving log to the assigned investigator.



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☞ The principal investigator will compare your improvement with the results from your 1st preoperative evaluation.

☞ Improvement will be rated on a 5-point scale.

IMPROVEMENT SCALE	
1	0-20%
2	21-40%
3	41-60%
4	61-80%
5	81-100%

☞ If your symptoms have improved by 80% or more:

- You will continue to shave daily for the next 90 days.
- You will be given a new shaving log and any needed shaving supplies.

☞ If your improvement is less than 80%:

- You will be considered to be a treatment failure and removed from the study.
- At that time you will resume your no shaving status.

At the 6th Month Postoperative Evaluation:

☞ You will submit your last 90-day shaving log to the assigned investigator.

☞ The principal investigator will compare your improvement with the results from your 1st preoperative evaluation.



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- ☞ If your symptoms are still improved by 80% or more:
 - You will be considered a treatment success.
 - *A recommendation to have your shaving profile removed will be submitted to your chain of command.*
 - You should continue to shave daily.

- ☞ If your improvement falls below 80%:
 - You will be considered a treatment failure and removed from the study. At that time, you will resume your no shaving status.

You will be given enough shaving supplies to last the entire duration of the study. However, you can contact an assigned investigator to get additional items if needed.

Pre-Treatment instructions:

- ⌘ Do not wax, tweeze, or use chemical depilatories (hair removal creams) at any time during the study.

- ⌘ Use only the Cetaphil Cleanser® given to you at the start of the study to wash your face. Do not use any other facial cleansers during the duration of the study.

- ⌘ Do not apply any topical medications to you face or neck during the study unless instructed to do so by the assigned investigator.

- ⌘ If you are prescribed any medications during a medical appointment, please inform one of the investigators at your next visit.

- ⌘ Please inform one of the investigators if there is any change to your current health status at your next visit.

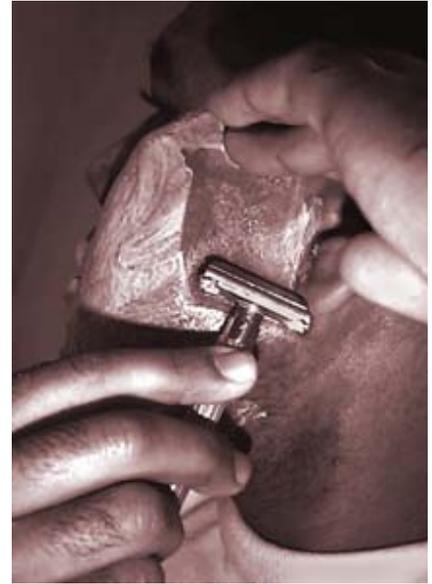


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Shaving Technique:

To minimize irritation and the development of razor bumps, follow the below instructions:

- ✎ If possible, take a hot shower for 10-15 minutes and wet shave using a shaving mirror while you are still in the shower.
- ✎ It is important to soften the beard area prior to shaving. Wash your face with the Cetaphil® cleanser provided to you.



If you can not shower:

- ✎ Take a face or washcloth and soak it in hot water.
- ✎ Apply the hot cloth to your face and neck for 3-5 minutes.
- ✎ Determine the direction of hair growth.
 - For most men, beard hair growth is downward. This can be confirmed by running the fingers downward on the beard. It should feel smooth, not rough.
- ✎ Apply Bump Fighter® shaving gel to your **wet face and beard.**
 - Ensure you apply enough to achieve a thick even application to all the areas.
- ✎ Use the Bump fighter razor® provided. The blades have a Bump Guard® to help minimize irritation.
- ★ *Change the blade after every five uses.*



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- ☞ Always begin by shaving the upper face (sideburns to upper jaw line).
- ☞ Start at the upper jaw line and shave to the lower jaw line using short light strokes.
 - Never shave against the direction of hair growth.
 - Never pull or stretch the skin when shaving.
 - Never shave repetitively over the same area.
 - Never try to shave too close, especially in the neck area.
 - Three strokes in the same area is the limit before severe irritation occurs.
 - Finish shaving the lower jaw line down to the end of the beard area.
 - Each stroke should be feather light.
- ☞ After shaving, rinse the face gently with warm water. (Never use cold water) Pat the skin dry with a cotton towel.

Post Treatment Instructions:

- ☞ You will have an anti-inflammatory steroid cream and an ice pack applied immediately following your laser treatment to help reduce any redness or swelling.
- ☞ After your treatment:
 - You may have a mild sunburn like sensation that typically lasts 2-3 hours.
 - The redness and swelling may last one or two days.



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- ☞ Treated areas should be *gently* washed twice per day with tepid water and the Cetaphil® cleanser that was provided to you.

- ☞ Blistering of the skin is possible.
 - The occurrence of blistering is rare, less than 2% of all cases reported to date, but it is possible.
 - Please contact the assigned investigator at the first sign of persistent pain or blistering lasting longer than 48 hours.

- ☞ Some patients develop crusting within the treated areas. If you develop crusting:
 - Expect a healing period similar to that which you experience with any minor skin abrasion.
 - If you feel there is a large amount of crusting and persistent pain, contact an investigator to be re-evaluated.

- ☞ Mild discomfort after treatment is expected. Tolerance to the discomfort varies from patient to patient. If you are experiencing discomfort:
 - You can take either an aspirin, an ibuprofen (Motrin), or an acetaminophen (Tylenol) as directed by the investigator as needed to reduce the discomfort.

When Resuming Normal Activities:

- ☞ Protect the skin from rubbing or abrasions and avoid contact sports until there is no evidence of irritation.

- ☞ Avoid swimming if there is any oozing or crusting of the skin.

- ☞ Watch for signs of infection:
 - Increased swelling
 - Tenderness
 - Redness, hot skin temperature
 - Pus-like drainage from treated areas:



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- Report any of these symptoms to an investigator as soon as possible.
- You should also be evaluated by your primary care provider.

Post treatment expectations:

- ☞ Hair loss and reduction of inflammation will be most evident 10 to 14 days after treatment.
- ☞ Two weeks after treatment you may experience what seems to be re-growth of hair, but actually isn't.
 - This is referred to as “shedding”. The hairs eventually release from the root and simply will fall out.
 - Gentle cleans your face as before and gentle wipe the areas with a moist warm cloth.

FREQUENTLY ASK QUESTIONS

Q: Will I ever need to shave again?

A: Yes! Not all of your facial hair will be permanently removed. The hairs that remain usually grow back much thinner and finer and no longer cause PFB. The goal of the study is to provide the proper amount of treatments that allows you to resume shaving daily without developing razor bumps.

Q: Will I be able to grow a beard when I get out of the Military?

A: Currently there are no long-term studies available to say for sure. Permanent hair reduction is defined by the FDA as elimination of hair growth or an interval greater than six months before hair begins to re-grow. However, most people with moderate to severe PFB are unable to grow a beard without developing painful bumps even without shaving.



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Contact Information for Investigators:

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