

## BMP Information and Informed Consent

Bone Morphogenetic Protein (BMP) is a bone growth promoting protein that your body produces naturally. A specific type of this protein named BMP-2 has been genetically engineered for commercial use, and was FDA approved in 2002 for promoting spine fusion during an anterior lumbar fusion surgery. It has been widely used outside of this specific indication ("off label") to promote bone healing and spine fusion for other types operations. Subsequent studies of BMP-2 have shown that there are additional side effects/risks from using BMP-2 that were either not reported or under-reported in the initial investigations. For instance, when used in the anterior/front of the cervical spine, it can cause life-threatening airway compromise. This prompted the FDA to release a warning about this use of BMP-2 in 2008. Currently, the following risks have been associated with the use of BMP-2:

- **Pain** – There has been an association of higher immediate post-operative pain in the first few months, but lower overall pain after that.
- **Heterotopic Bone Formation** – This is formation of bone in and around the soft tissues where the surgery was performed. This may result from over-stimulation of the bone cells.
- **Radiculitis** – This is irritation of the nerves from inflammation, which can cause any combination of pain, numbness or weakness.
- **Osteolysis** – The inflammation that occurs around the surgical site can actually lead to resorption of bone, which can cause problems with the implants used during your surgery and may require another surgery to fix this.
- **Seroma** – This is fluid collection in the surgical site. This can happen after any type of spine surgery, but may be more common after using BMP. Sometimes this would have to be drained surgically.
- **Dysphagia** – A higher chance of having swallowing trouble has been described if you have BMP used in the front of your neck. This is a common complication of any surgery in the front of the neck, but using BMP may increase the risk of this.
- **Retrograde Ejaculation** – When BMP is used in the front of the lumbar spine it can cause irritation of the nerves that control ejaculation in men.
- **Bone Overgrowth** – Sometimes BMP may cause bone to grow in places where it causes new nerve compression, which may then cause any combination of pain, numbness or weakness. This may require another surgery to remove the excess bone.
- **Airway Compromise/Death** – When used in the front of the neck, BMP may cause swelling that obstructs or closes your airway. Death has been reported from using BMP in the front of the neck, but is extremely rare.
- **Cancer** – While BMP does not turn a normal cell into a cancer cell, there are basic science studies that suggest that it may cause cancer cells to grow faster, like a fertilizer. Further, there are some clinical studies showing that patients are at a higher, but still very low, risk of developing cancer. If you have any history of cancer, we will not use it.

So why does Dr. O'Neill recommend BMP in your case? There is evidence that it may help you heal the bone. If you are a smoker, diabetic, have had problems healing bone in the past or are having many levels fused, there is a risk of the bone not healing. If this occurs, the implants used during your surgery would likely fail, and you would be at risk for requiring another surgery to fix this. Alternatives to using BMP-2 include using cadaver bone alone, taking bone from your pelvis through another incision, using other commercially available products, or doing additional surgical procedures to increase your chance of successfully healing the bone. Dr. O'Neill is only interested in doing what is best for you, and will do everything possible for you to have the best possible outcome, regardless of whether you agree to use BMP during your surgery or not.

I have reviewed this document and have discussed the risks and benefits of using BMP with Dr. O'Neill. I understand the risks and benefits to using BMP during my spine surgery, and agree to have it used during my surgery.

Patient name (print): \_\_\_\_\_

Patient signature: \_\_\_\_\_ Date: \_\_\_\_ / \_\_\_\_ / \_\_\_\_