



Duke Neurosurgical Associates of Lumberton
AN AFFILIATE OF DUKE UNIVERSITY HEALTH SYSTEM

Charles S. Haworth, M.D.

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Document Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
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To Whom It May Concern:

I am writing with regards to the docket #97N-484S. Apparently, the FDA is considering imposing regulations on bone graft material to say that it is a medical device.

I have been doing cervical fusion and also lumbar fusions for roughly 20 years. I have used a variety of bone materials during that time. Several particular items that have come along recently, I think, are certainly superior products and have enhanced the way that we fix people.

The first of these is the impacted posterior lumbar interbody fusion bone graft which is marketed by Sofamor Danek. Until recently I was using interbody fusion cages. I have now switched over to using the impacted PLIF grafts in conjunction with pedicle screws. I cannot begin to tell you how well the patients are doing and how well this product is performing. The old criticisms of not being able to see the fusion occur are now negated by the fact that the disc space is full of bone. I think that using this device in conjunction with pedicle screws allows immediate and solid stabilization of the segments in the lumbar spine to further enable an excellent result. Less retraction of the nerve roots is required to insert the PLIF grafts, and as a result, I am seeing less nerve damage as opposed to using the cages.

I have used over 100 individual pieces of bone with regards to this product. The bone products have always performed satisfactorily. There have been no "crush failures" and no back-outs occurring. I am extremely satisfied with this device and so are my patients.

Other advantages of this device are that the bone products are uniformly machined and have an excellent method of introduction into the disc space. This enables the bone products to be put in safely and it also assures that we get a satisfactory bone product each time. With the patient's own bone we get a variety of bone pieces and sizes and also quality of bone. In the past it has been difficult to get autograft or allograft tricortical iliac crests to adequately fit the need of a PLIF graft. As a result, I have seen problems with poor fit and collapse of the tricortical PLIF grafts. Another advantage of the impacted PLIF bone graft is that it can be used in conjunction with the patient's own bone in order to fill the disc space up with bone and achieve a better fusion. The impacted PLIF graft also helps restore



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the normal lordosis of the lumbar spine which is not readily possible with any other type of bone graft product.

It has come to my attention that one of the reasons that the FDA has considered regulating bone allografts as medical devices, is because they have been instigated into doing so by the Sulzer Spine-Tech Medical Group. You must realize that because of the superiority of this bone graft material many surgeons are now switching to use the impacted PLIF graft as opposed to the Sulzer BAK cages. This has, of course, diminished Sulzer's business and as a result they are trying to get the FDA to sabotage the competition. This is not fair to the surgeons who are using the product nor to the patients who are counting on access to these superior and reliable products.

The other new product that I am using is the Cornerstone cortical bone grafts in the neck. Once again, these bone products are premodified to be within tight size constraints. The cortical graft itself is quite strong and prevents collapse as the graft is incorporated. It is certainly much stronger than the traditional tricortical iliac crest allografts that I have used for many years. Because the center of the Cornerstone graft is hollow, it can be packed with the patient's own bone and this also helps achieve a faster fusion. The graft is used with a plate. I have now used upwards of 100 Cornerstone grafts, again with no failures or collapse. There has also been no extravasation of the grafts from the disc space once placed. The use of the Cornerstone grafts speeds up operative time. The risk of complication secondary to iliac bone graft harvest has been eliminated.

In summary, both of these grafts represent an advance in bone technology. Because they can be supplied to us in various uniform yet consistent sizes and quality, we are able to cut down on our surgical time. We are getting better technical results. Both grafts are always used in conjunction with the patient's own bone to help healing. I have never seen a failure resulting from the graft itself.

I would urge the FDA to reconsider restricting access to these superior developments in bone technology. I do not think that the FDA should allow itself to be used as a weapon by the competition. In this situation I think that both the surgeons and the patients should determine if the products are superior and if so, they will continue to be used. Thank you very much for your consideration.

Sincerely,

A handwritten signature in cursive script, appearing to read "Charles S. Haworth". The signature is written in dark ink and is positioned above the typed name.

Charles S. Haworth, M.D.

CSH/lr/Dictated but not read

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