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L. SUMMARY OF SAFETY AND EFFECTIVENESS

The application of ice after surgery or injury to reduce swelling and pain is a well established treatment with well know indications and contraindications. Devices approved for market, such as the Breg Inc. Polar Care 500, the Burke/Nutech Inc. Sports Therapy 1000, and the Smith & Nephew DonJoy, Inc. Model 1100 device, are essentially more convenient and safer means to apply ice. More convenient because of less bulk for example, and safer because the treatment temperature can be set above the melting temperature of ice, 32F (0C), allowing extended safe treatment. A bag of ice in contrast, will necessarily be at 32F (0C) without option.

The device consists of a tank containing ice and water, a water pump to circulate cold water, a console containing a means to control and indicate temperature and a pad through which the cold water circulates. The pump, contained in a waterproof case, is submerged in the ice water bath and connected to the console via insulated tubing through which the chilled water flows to and from the pad. The console is located along this tubing about halfway between the pad and the water bath for easy access by the patient. Leakage current for the device shall not exceed 100uA.

To our knowledge, no new safety issues regarding the use of these and like devices approved for market, have been raised. To the contrary, the literature continues to study the benefits of cold therapy. Some recent publications follow:

Bert, Stark, Maschka, Chock. The Effect of Cold Therapy on Morbidity Subsequent to Arthroscopic Lateral Retinacular Release, *Orthopaedic Review*, Vol. XX, No. 9, September 1991

Ho, Coel, Kagawa, Richardson. The Effect of Ice on Blood Flow and Bone Metabolism in Knees, *The American Journal of Sports Medicine*, Vol. 22, No. 4, 1994

Ho, Illgen, Meyer, Comparison of Various Icing Times in Decreasing Bone Metabolism and Blood Flow in the Knee, *The American Journal of Sports Medicine*, Vol. 23, 1995

Grana WA, Cold Modalities (Chapter 7) in: Orthopedic Sports Medicine, Ed. Delee, Drez Vol 1, 1994

Smith & Nephew DonJoy Inc.

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