

## **RESHAPING FAT BY CRYOLIPOLYSIS**

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Published animal studies and unpublished controlled human studies have demonstrated that cryolipolysis (cold-induced apoptotic fat cell death) can safely reducing the thickness of the subcutaneous fat layer without damage to the overlying skin or associated structures.

A multi-center, prospective, non-randomized, IRB-approved study enrolled male and female subjects >18 years of age with clearly visible fat on the flank or back appropriate for treatment with cryolipolysis. Cooling was applied by a prototype device to the treatment area using pre-programmed treatment profiles that control the rate of heat extraction and duration of treatment. A contralateral untreated area (e.g., the opposite flank or portion of the back) was maintained as a control. Efficacy was evaluated by ultrasound measurement of fat layer reduction, comparison of pre and post-treatment photographs and physician assessment.

Based on interim results, photographic, ultrasound and physician assessment confirm that cryolipolysis results in a visible contour change in a majority of subjects. Ultrasound measurements taken on a subset of 10 subjects demonstrated a fat layer reduction in 100% of these subjects with an average reduction of 22.4% at four months post-treatment. Subjects presenting with modest fat bulges had the best cosmetic results. There were no device related adverse events reported.

Selective cryolipolysis results in reductions in subcutaneous fat volume without damage to the surrounding tissues. While all subjects for whom ultrasound images were obtained showed a significant reduction in fat layer, cosmetic improvement was more readily observed in subjects with modest fat bulges. Further studies of fat reduction effects in other anatomical areas with optimized treatment parameters are ongoing.