

### Nitinol Frame

The frame is the skeleton needed to give the implant the required mechanical strength while maintaining flexibility and soft touch due to the super elasticity of the Nitinol. Nitinol alloys has long become integral to the design of a variety of new medical products. The enormous elasticity of these alloys is the most dramatic advantage afforded by this material, together with features such as biocompatibility, kink resistance, constancy of stress, physiological compatibility, shape-memory deployment, dynamic interference, and fatigue resistance.

The nitinol frame is cut from a Super elastic Nitinol tube and laser cut to its unique floral pattern. Following visual inspection, the frames are then heat treated utilizing a dedicated jig to achieve the floral geometry. The frames are then subjected to electro-polishing process (to create smooth surface finish as well as an oxide layer for corrosion resistance).

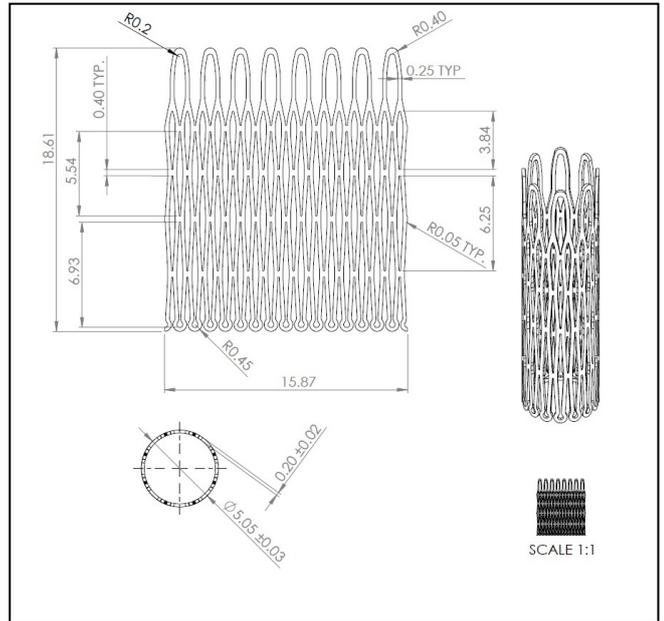


Figure 4: The FixNip NRI Nitinol Frame

### Silicon Overmolding

The Nitinol frame is fully encapsulated with the Silicone, minimizing direct contact between the Nitinol frame and patient's tissue.

FixNip chose a low durometer Silicone for the encapsulating of the Nitinol frame in order to maintain the super elasticity of the Nitinol frame and provide the implant the soft touch required considering the application requirements.

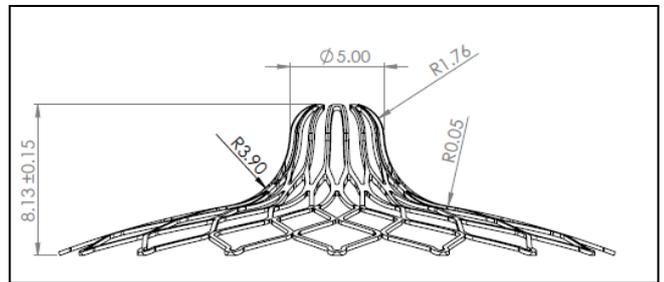


Figure 5: The FixNip NRI Heat Shaped Nitinol Frame

Liquid Silicone rubbers, or LSRs, are elastomer systems reinforced with silica. They contain functional polymers of lower average molecular weight and viscosity when compared to high consistency rubbers (HCRs). LSRs are designed for overmolding processes. LSR refers to a two-part, translucent Silicone system designed for use with injection molding equipment. LSR cures with heat via addition-cure chemistry. FixNip uses NuSil Technology's MED-4810 Silicone Rubber, LSR. NuSil LSRs offer outstanding physicals and lot-to-lot consistency, optimizing product design in an easy-to-process formulation, improving cycle time and part quality. These high-performance materials are produced and packaged in ISO 8 and ISO 7 clean rooms.

Figure 6: Laser Markin

