

## STATEMENT REGARDING SAFETY MEMBRANE

All Nouveau Contour needle cartridges are equipped with a safety membrane.

This safety membrane is made of biocompatible silicone and serves multiple safety functions:

1. The primary function of the safety membrane is sealing. The safety membrane divides the needle system into a 'potentially contaminated' and a 'clean' compartment. This design prevents pigment, wound fluid, or blood from entering the handpiece from the module. It effectively blocks the transfer of germs that may be present in the handpiece to the needle cartridge.
2. The needle module has a safety system that ensures the needle only extends from the tip when it is attached to the handpiece and the device is turned on. When the needle module is removed from the handpiece after use, the needle retracts fully into the module, preventing accidental pricks from the used needle.
3. When the needle cartridge is inserted into the handpiece, the safety membrane is slightly tensioned. This presses the needle shaft against the motor rod, which counteracts needle fluctuations.

The functionality of this design has been tested under various conditions by several accredited testing laboratories. It has been proven that the safety membrane is effectively impervious to penetration by viruses, bacteria, yeast, or fungi.

To ensure consistent product quality, all components of the needle cartridge are tested during development and production. Each needle cartridge is individually checked. This process is certified according to ISO 13485.

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A handwritten signature in black ink, consisting of several overlapping loops and a long horizontal stroke extending to the right.

Nouveau Contour HQ  
Burgemeesterlaan 2  
6002 EG Weert  
The Netherlands