

## Statement regarding safety membrane

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All needle cartridges manufactured and marketed by MT.DERM GmbH contain a so called safety membrane. This safety membrane is made of biocompatible silicone and fulfills several safety functions:

- 1) It secures the needle shaft assembly to the cartridge body and retracts the needle tip into the cartridge before and after use. The risk of an unintended injury is thereby reduced significantly.
- 2) When inserted into a handpiece, the safety membrane is slightly tensioned and presses the needle shaft against the engine rod, hereby reducing all sounds associated with rattling.
- 3) The most important function is sealing. The safety membrane divides the needle system in a potentially contaminated and a clean compartment. This design effectively prevents either contaminated color or body fluids from entering the handpiece as well as preventing pathogens that may be presented in the handpiece to enter the needle cartridge.

The functionality of this concept has been tested in various settings by several accredited test laboratories and is proven to be highly effective. For example, analysis of the integrity of the safety membrane regarding penetration by Hepatitis B virus under worst case scenario did not result in penetration of the safety membrane by viral particles, protein or hemoglobin molecules. This test clearly demonstrates that the safety membrane is safe towards penetration by viruses, bacteria, yeast or fungi.

To ensure a constant product quality, all needle cartridge components are tested during development and production. Every single needle cartridge is checked individually before it leaves the company. Our ability to do so has been proven for all our tattoo and cosmetic needle cartridges as well as for all our medically approved safety cartridges by certification of our quality management system according to ISO 13485.



**Figure 1:** Several families of needle cartridges manufactured and marketed by MT.DERM GmbH (safety membrane is shown in red)

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