

# Fill4Sure™ Filling Needles



Fill4Sure<sup>™</sup> Filling Needles provide a needle for every drug product application or filling machine. An offering of both ready-made and tailor-made needles provides 100% coverage across the fill-finish arena, uncoupling the restrictions posed by OEM needles. Fill4Sure<sup>™</sup> Filling Needles are made from premium 316L stainless steel with polycarbonate housings in an oil- and adhesive-free manufacturing process. Filling speed, precision and accuracy are at the heart of the design process.

- Repeatable performance and affordability in a single-use format
- · Oil- and Adhesive-free manufacturing
- Standard and Custom needle designs
- Premium healthcare grade construction materials
- Co-axial filling needle available for gas-overlay filling of oxygen sensitive drug products
- Filling Needle ID range from 0.8 mm to 9.0 mm

| Features                                | Benefits  |
|---|---|
| Single-use, ready to use                | <ul> <li>Open, sterilize and fill;</li> <li>Increase productivity through decreases in set-up times</li> </ul>  |
| Made-to-fit                             | <ul> <li>Needles designed for compatible fit not proprietary fit</li> <li>Needles available for any filling machine configuration with full customization available</li> </ul>  |
| Repeatable Performance                  | <ul> <li>Consistent Performance: Confidence in product uniformity across batches is<br/>achieved by conducting meticulous quality control checks, ensuring needle<br/>equivalence with each production run.</li> <li>Material lot qualification for consecutive construction standards</li> </ul> |
| Needle Straightness                     | <ul> <li>Needle straightness of &lt; 2mm/M for high-speed filling</li> </ul>  |
| Premium Construction<br>Materials       | <ul> <li>ISO9626 lot verified 316L stainless steel</li> <li>USP Class VI, healthcare grade polymer machine housings certified to 21CFR177.1580</li> <li>Latex-, phthalate-, RoHS- and REACH-free materials</li> </ul>   |
| Oil- and Adhesive- free<br>Construction | <ul> <li>Minimize introduction of foreign particles into the filling environment</li> <li>No additional cleaning required, further minimize set-up time and quality control procedures</li> </ul>   |



## Materials

- Needle Tubing: 316L stainless steel – ISO 9626 lot certified
- Needle Housing: USP Class VI healthcare grade polycarbonate – certified to 21CFR177.1580
- REACH, RoHS, phthalate and latex free

## Packaging

 70% IPA cleaned in a HEPA-filtered Class 7 environment prior to double-bagging.

### Sterilization

- Autoclave
- Gamma-irradiation (max 50kGy)

# Applications

- Final-fill automated filling for drug products, cell and gene therapy and formulations.
- Benchtop filling applications for clinical trial sized production.
- Gas-overlaying for oxygen-sensitive drug products.

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