

Technical Requirements for Medical Device Products

Product Name: Disposable Sterile Press Needle

1. Product Models/Specifications and Classification Criteria

1.1 The type and basic dimensions of the press needle shall comply with Figure 1 and Table 1.

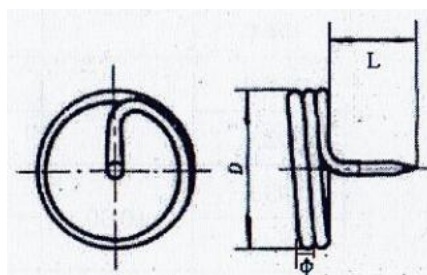


Figure 1: Press Needle Type Diagram

Table 1: Basic Dimensions and Tolerance Limits of Press Needles

Units: Millimeters (mm)

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Specification	φ		D		L		
	Diameter	Tolerance	Head Diameter	Tolerance	Length	Tolerance	
0.16×1.7	0.16	±0.008	Φ2.0	±0.20	1.7	±0.30	
0.16×1.7			Φ2.6		1.7		
0.16×1.7			①3.0	±0.30	1.7		
0.16×1.7			Φ4.0		1.7		
0.18×0.9	0.18		Φ2.0	±0.20	0.9		±0.30
0.18×0.9			Φ2.6		0.9		
0.18×0.9			Φ3.0	±0.30	0.9		
0.18×0.9			Φ4.0		0.9		
0.18×1.1			Φ2.0	±0.20	1.1		
0.18×1.1			Φ2.6		1.1		
0.18×1.1			Φ3.0	±0.30	1.1		
0.18×1.1			Φ4.0		1.1		
0.18×1.2			Φ2.0	±0.20	1.2		
0.18×1.2			Φ2.6		1.2		

Table 1: Basic Dimensions and Tolerance Limits of Press Needles

Units: Millimeters (mm)

Specification	Φ		D		L	
	Diameter	Tolerance	Head Diameter	Tolerance	Length	Tolerance
0.18×1.2	0.18	±0.008	Φ3.0	±0.30	1.2	±0.30
0.18×1.2			Φ4.0		1.2	
0.18×1.35			φ2.0	±0.20	1.35	
0.18×1.35			Φ2.6		1.35	
0.18×1.35			Φ3.0	±0.30	1.35	
0.18×1.35			Φ4.0		1.35	
0.20×1.0	0.20	±0.008	Φ2.0	±0.20	1.0	
0.20×1.0			Φ2.6		1.0	
0.20×1.0			Φ3.0	±0.30	1.0	
0.20×1.0			Φ4.0		1.0	
0.20×1.2			Φ2.0	±0.20	1.2	
0.20×1.2			Φ2.6		1.2	
0.20×1.2			Φ3.0	±0.30	1.2	
0.20×1.2			Φ4.0		1.2	
0.20×1.3			Φ2.0	±0.20	1.3	
0.20×1.3			Φ2.6		1.3	
0.20×1.3			Φ3.0	±0.30	1.3	
0.20×1.3			Φ4.0		1.3	
0.20×1.5			Φ2.0	±0.20	1.5	
0.20×1.5			Φ2.6		1.5	
0.20×1.5			Φ3.0	±0.30	1.5	
0.20×1.5			Φ4.0		1.5	
0.20×1.6			Φ2.0	±0.20	1.6	
0.20×1.6			Φ2.6		1.6	
0.20×1.6			Φ3.0	±0.30	1.6	
0.20×1.6			Φ4.0		1.6	
0.20×2.0			Φ2.0	±0.20	2.0	
0.20×2.0			φ2.6		2.0	
0.20×2.0			Φ3.0	±0.30	2.0	
0.20×2.0			Φ4.0		2.0	

Table 1: Basic Dimensions and Tolerance Limits of Press Needles

Units: Millimeters (mm)

Specification	Φ		D		L	
	Diameter	Tolerance	Head Diameter	Tolerance	Length	Tolerance
0.20×2.5	0.20	±0.008	Φ2.0	±0.20	2.5	±0.30
0.20×2.5			Φ2.6		2.5	
0.20×2.5			Φ3.0	±0.30	2.5	
0.20×2.5			Φ4.0		2.5	
0.22×1.0	0.22	±0.015	Φ2.0	±0.20	1.0	
0.22×1.0			Φ2.6		1.0	
0.22×1.0			D3.0	±0.30	1.0	
0.22×1.0			Φ4.0		1.0	
0.22×1.2			Φ2.0	±0.20	1.2	
0.22×1.2			Φ2.6		1.2	
0.22×1.2			φ3.0	±0.30	1.2	
0.22×1.2			Φ4.0		1.2	
0.22×1.3			Φ2.0	±0.20	1.3	
0.22×1.3			Φ2.6		1.3	
0.22×1.3			Φ3.0	±0.30	1.3	
0.22×1.3			Φ4.0		1.3	
0.22×1.5			Φ2.0	±0.20	1.5	
0.22×1.5			Φ2.6		1.5	
0.22×1.5			φ3.0	±0.30	1.5	
0.22×1.5			Φ4.0		1.5	
0.22×1.6			φ2.0	±0.20	1.6	
0.22×1.6			Φ2.6		1.6	
0.22×1.6			Φ3.0	±0.30	1.6	
0.22×1.6			Φ4.0		1.6	
0.22×1.7			Φ2.0	±0.20	1.7	
0.22×1.7			Φ2.6		1.7	
0.22×1.7			Φ3.0	±0.30	1.7	
0.22×1.7			Φ4.0		1.7	
0.22×2.0			Φ2.0	±0.20	2.0	
0.22×2.0			Φ2.6		2.0	

Table 1: Basic Dimensions and Tolerance Limits of Press Needles

Units: Millimeters (mm)

Specification	Φ		D		L		
	Diameter	Tolerance	Head Diameter	Tolerance	Length	Tolerance	
0.22×2.0	0.22	±0.015	Φ3.0	±0.30	2.0	±0.30	
0.22×2.0			Φ4.0		2.0		
0.22×2.5			Φ2.0	±0.20	2.5		
0.22×2.5			Φ2.6		2.5		
0.22×2.5			Φ3.0	±0.30	2.5		
0.22×2.5			Φ4.0		2.5		
0.22×3.0			Φ2.0	±0.20	3.0		
0.22×3.0			Φ2.6		3.0		
0.22×3.0			Φ3.0	±0.30	3.0		
0.22×3.0			Φ4.0		3.0		
0.25×1.0			0.25	Φ2.0	±0.20		1.0
0.25×1.0				Φ2.6			1.0
0.25×1.0	Φ3.0			±0.30	1.0		
0.25×1.0	φ4.0				1.0		
0.25×1.5	φ2.0			±0.20	1.5		
0.25×1.5	Φ2.6				1.5		
0.25×1.5	Φ3.0			±0.30	1.5		
0.25×1.5	Φ4.0				1.5		
0.25×2.0	Φ2.0			±0.20	2.0		
0.25×2.0	φ2.6				2.0		
0.25×2.0	φ3.0			±0.30	2.0		
0.25×2.0	φ4.0				2.0		
0.25×3.0	Φ2.0			±0.20	3.0		
0.25×3.0	Φ2.6				3.0		
0.25×3.0	Φ3.0	±0.30		3.0			
0.25×3.0	Φ4.0			3.0			
0.26×1.5	0.26	Φ2.0		±0.20	1.5		
0.26×1.5		Φ2.6			1.5		
0.26×1.5		Φ3.0	±0.30	1.5			
0.26×1.5		Φ4.0		1.5			

1.2 Press needles shall be made of 06Cr19Ni10 (SUS304) stainless steel wire as specified in GB/T 4240-2009.。

2. Performance Requirements

- 2.1 Basic dimensions and tolerance limits shall comply with Section 1.1.
- 2.2 The needle tip shall be sharp, round, and free of burrs or hooks. After applying 0.4N pressure, the puncture force shall not exceed 0.7N.
- 2.3 Needle hardness shall be $\geq 450\text{HV}0.2$.
- 2.4 The needle body shall be free of scratches, bends, or pitting.
- 2.5 Surface roughness (Ra) of the needle body and tip shall not exceed $0.4\mu\text{m}$.
- 2.6 The needle ring shall be round, tightly arranged (1 or 2 loops), and aligned vertically with the needle body without gaps.
- 2.7 The press needle shall exhibit corrosion resistance.
- 2.8 The press needle shall be sterile.
- 2.9 Ethylene oxide residue shall be $\leq 10\mu\text{g/g}$.

3. Test Methods

- 3.1 **Visual Inspection:** Observe under 10x magnification for compliance with Sections 2.2, 2.4, and 2.6.
- 3.2 **Surface Roughness:** Compare with standard roughness samples (Section 2.5).
- 3.3 **Dimensions:** Measure with standard tools (Section 2.1).
- 3.4 **Performance Testing:**
 - 3.4.1 **Tip Sharpness:** Follow Appendix A (Section 2.2).
 - Hardness:** Test per GB/T 4340.1-2009 (Section 2.3).
 - Corrosion Resistance:** Immerse in 10% citric acid for 5h, boil in distilled water for 30min, and air-dry. No rust permitted (Section 2.7).
 - Sterility:** Sample 40 units per batch; test per Chinese Pharmacopoeia 2015 Edition (Section 2.8).
 - Ethylene Oxide Residue:** Analyze per GB/T 14233.1-2008 (Section 2.9)