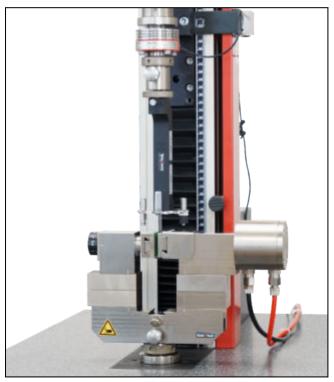


ISO 11040-4/-6 Annex G6, Method 2 - Pull-off force of needle shield (tip cap)



Test arrangement with pneumatic grips and self-aligning tension grips



Detail view with needle shield (tip cap)

#### **Applications**

CTA: 167332 133009

Testing is performed on glass or plastic syringe barrels for injectables and sterilized subassembled syringes ready for filling.

To perform the test, the syringe is gripped with the lower pneumatic grip, Fmax 500 N.

The needle shield (tip cap) is pulled axially upwards off the syringe with the self-aligning tension grips. The test speed is between 100 mm/min and 1000 mm/min. The pull-off force and the pull-off distance are measured and recorded.

The expected force range is 15 N.

The test results contain the following information:

- Sampling rate
- Test speed
- Maximum force and force-displacement curve

- Number of syringes
- Deviations

#### **Advantages and features**

- Special self-aligning tension grips for different needle shield sizes
- Secure gripping of sensitive specimens through adjustable gripping pressure
- high stiffness and precise crosshead guidance with zwickiLine
- maximum safety for user, test results, specimen material and testing system.
- online correction of machine compliance guarantees very high travel-measurement and positioning accuracy
- traceable, reliable test results in accordance with FDA 21 CFR Part 11, guaranteeing complete, tamperproof documentation of all actions and changes performed in the testXpert Illtesting software



ISO 11040-4/-6 Annex G6, Method 2 - Pull-off force of needle shield (tip cap)

#### **Technical data**

Type Item No.	Self-aligning tension g	Self-aligning tension grips for medical components 1037567	
Туре	8050		
Operating principle/identification	Simple specimen insertion	Simple specimen insertion	
Test load F <sub>max</sub>	0.5	kN	
Dimensions			
Height	155	mm	
Width	65	mm	
Depth	65	mm	
Connection, stud	Ø 8	mm	
Ambient temperature	+10 +35	°C	
Weight per specimen grip, approx.	281	g	
Scope of delivery	1	pieces	

## Pneumatic specimen grips type 8097

Item No.	1106823	
Туре	8097	
Operating principle/identification	Opposing jaw with stepped and stepless adjust- ment	
Test load F <sub>max</sub>	0.5	kN
Operating pressure	1 10	bar
The operating pressure depends on the upstream components.		
Gripping force at 6 bar	0.75	kN
Gripping force at 10 bar	1.3	kN
Opening width with jaws, 5 mm thickness <sup>1)</sup>	20	mm
Gripping travelof pneumatically operated side	10.5	mm
Gripping of the specimen	The specimen must be gripped with at least 2/3 of the jaw height.	
Dimensions		
Height	95	mm
Installation height	110	mm
Width	242	mm
Depth	60	mm
Depthwith connection unit	86	mm
Connection, hole	Ø 20	mm
Weight per specimen grip, approx.	1.5	kg
Ambient temperature	+10 +35	°C
Scope of delivery	1	piece(s)

<sup>1)</sup> The opening width is the result of using jaws with 5 mm jaw thickness.



ISO 11040-4/-6 Annex G6, Method 2 - Pull-off force of needle shield (tip cap)

## **Accessories required**

## Jaws (1 x required)

Item No.	Specimen thickness [mm]	Ambient temperature [°C]	Scope of delivery [pieces]
3003408	Ø 12 to 35	-15 to +40	1 pair = 2
3003407	Ø 5 to 12	-15 to +40	1 pair = 2

#### Spacers (1x required)

Description	ArticleNumber
Spacers, height 20 mm, for increasing the free space between jaw and grip body. Scope of	316559
delivery 2 pieces. 2 pieces required per grip. <sup>1)</sup>	

<sup>1)</sup> For convenient operation

### Pneumatic control unit (1x required)

The pneumatic control units can be used with testXpert III V1.7 (from 14.12.2022) and testControl II V8.62.

Description	ArticleNumber
Pneumatic control unit	1108557
or	
Pneumatic control unit with clamping pressure preselection via testXpert III testing software	1108559

### Pneumatic hoses (1x required)

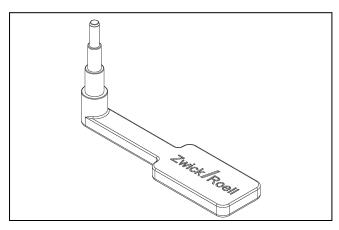
Description	ArticleNumber
Set of pneumatic hoses for connecting a pair of pneumatic grips; including hose guiding for strain	1112640
relief	

#### **Optional accessories**

Description	ArticleNumber
Holder For Inserting Prefilled Syringes into Pneumatic Grips (e.g. ISO 11040	1075238
Annexes G1, G3, G6)	
- The insertion aid enables easy insertion of the syringes into the specimen grip, without risk of	
pinching or injury.	
- The holder is suitable for prefilled syringes in sizes 0.5 ml, 1.0 ml, 1.5 ml, and 5 ml	



ISO 11040-4/-6 Annex G6, Method 2 - Pull-off force of needle shield (tip cap)



Holder For Inserting Prefilled Syringes