Sticking Point: An Examination of Needle and Syringe Force Testing

Needles and syringes must perform precisely to specification or they may seriously limit the ability of a healthcare professional to effectively and safely treat their patient. Force and torque testing in development and production enables the manufacturers to guarantee consistent quality and performance of their products. This article examines seven typical testing applications within this field.By David Mercer

Billions of syringes and single-use needles are produced annually, from hypodermic and surgical needles, to lancets and winged infusion sets. With ever-increasing demand to drive down mass production costs, and the frequent introduction of new safety-oriented devices, it is a continuously developing market.

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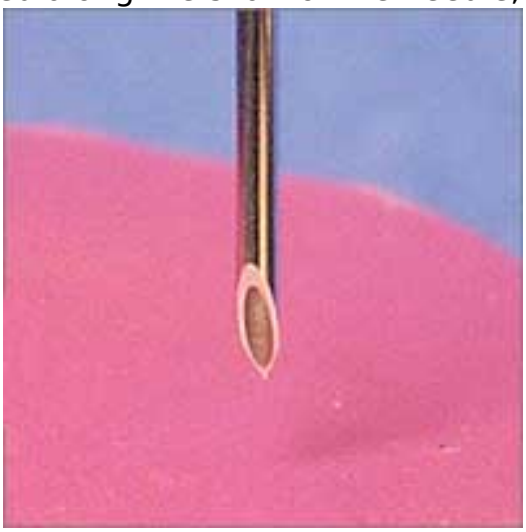
Assessing the mechanical properties of needles and syringes is a crucial ingredient in the successful development and production of such devices. Force and torque testing is a simple, fast, and relatively inexpensive method of quantifying the critical physical attributes of these products. It allows manufacturers to quickly identify and amend production errors that not only harm the brand’s reputation, but also jeopardize the safety and comfort of the patient. It also helps designers to perfect the usability and fitness-for-purpose of their devices, while striking an optimum balance between material usage and mechanical strength, and ensuring all new products conform to international standards.

The following examines seven key application areas for force and torque testing of needles and syringes, considering, in turn, the purpose, benefits, and considerations of each test, and where appropriate, describing how they are typically performed.

Needle Insertion and Penetration Forces

To maximize patient comfort, it is essential that a clean insertion and extraction of the needle is achieved, resulting in minimum trauma to the epidermis and subcutaneous tissue. Malformed and insufficiently sharp needle points can cause considerable pain on insertion, easily preventable with a well-designed and consistently produced device. Needle penetration and extraction forces are measured in development and production to characterize point sharpness, the frictional forces experienced along the shaft of the needle, and the effectiveness of the beveled tip geometry.



Penetration testing of hypodermic needles assesses point sharpness and geometry.

Threaded luer lock connectors undergo torque testing to assess joint strength and ease of operation.

The test typically requires a motorized force testing system, with a specialized lower fixture to hold in place a stretched foil of PVC or PU over a steel ring to simulate skin. The needle, which is mounted onto a sensitive, low capacity load cell, is brought down through the foil at a constant rate by the system's motorized crosshead travel. A computer-controlled system will provide a real-time graphical force profile, which may be analyzed for key areas of interest, including:
The initial peak force at which the needle tip first penetrates the foil
The force required for the beveled edge to continue through the hole, cutting it open wider
The frictional force experienced as the needle shaft slides through the hole, once the bevel has been passed

Needle-to-Hub Retention Strength

Needles are held within their hub by a variety of methods, including bonding, molding, welding, mechanical interlocking, and sealing. The retention strength of the assembly method must be sufficiently high to avoid disassembly or seal failure in use.

To test retention strength, the test system is normally fitted with an aluminum mounting block, beneath which the hub is placed with the needle tip exposed vertically. In the case of smaller needles and lancets, a lever-operated pin vice may be fitted to the tip, and an axial tensile load applied at a constant rate, until the needle is completely dislodged from the hub. For larger gage needles, a small wedge grip may be required to hold the sample. This test is performed in conformance with international standard ISO 7864.

Surgical Needle Crimp Strength

Single-use surgical needles are supplied connected to a length of suture via a

crimped end. This may take the form of a drilled-end crimp, in which a small aperture is made in the end of the needle, the suture threaded inside, and the needle pressed around it. Alternatively it may be a flange-type crimp, in which the needle end is pressed into a semi-circular formation, the suture placed into the groove, and either end of the semi-circle closed around it. The pull-off force of the needle from the suture must be sufficiently high to ensure it does not come away during placement of the sutures, but sufficiently low to enable surgeons to pull the needle from the suture as required, to allow quick and safe knot tying.

To perform the pull-off test, the needle is held in a small wedge grip, while the suture material is wrapped around a cable cam grip. This spreads the load evenly to avoid slippage during testing. A tensile load is then applied at a slow, steady rate until the suture is dislodged from the crimp. The maximum tensile force experienced is recorded as the crimp retention strength.

Needle Materials Testing

The steel needle itself must be produced to a consistently high standard of quality. Force testing should play an integral role in both production (as inline checks at steel formers and supplied materials quality checks at assemblers), and in development, to identify opportunities to reduce material usage without compromising functionality.

Tensile Strength

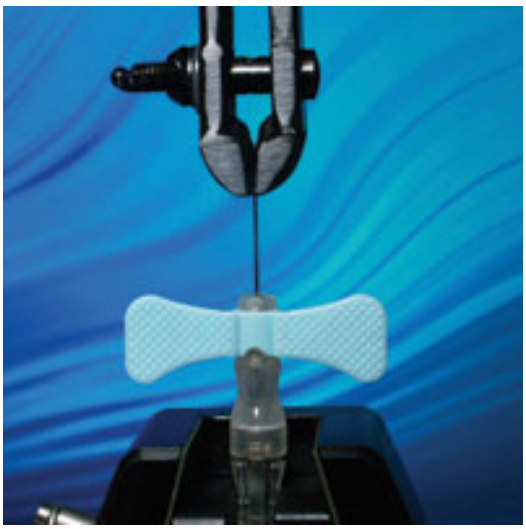
This simple mechanical test enables quantification of the material properties of the needle, and identification of areas of recurring weakness. The steel needle is held at either end by pneumatic grips, which exert an adjustable pressure suited to the gage of needle, eliminating early failure at the jaw face. It is common to thread small inserts into the needle ends to avoid collapse. The pneumatic grips should have lightly serrated faces to avoid sample slippage under loading. An axial tensile load is steadily applied until a clean break occurs in a central portion of the needle, clear of the grips.

Three-Point-Bend

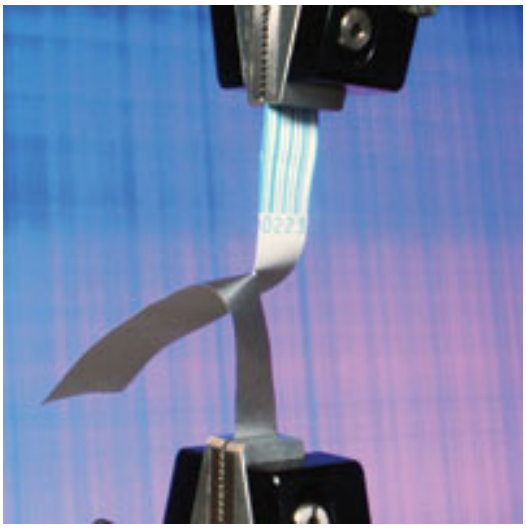
The three-point-bend test is used to assess the stiffness of the needle, and hence the likelihood of permanent deformation on insertion. The test requires the use of a specialized fixture, comprising two adjustable lower support anvils on which the sample is placed, and a single upper anvil mounted onto the motorized crosshead of an automated testing machine. The upper anvil descends to a pre-determined height, effectuating a bend in the center of the sample. Analysis of the load at a varying vertical displacement allows calculation of the Young’s Modulus of the needle, a useful measure for characterizing its expected behavior under typical loading in use.

Torque Assessment of Luer Lock Connectors

Needle hubs attach to syringes (and other devices) via push/pull taper luer, or threaded luer lock connectors. The force or torque required to disassemble the two elements must be high enough to avoid failure in operation and ensure a hermetic seal in the connection, yet low enough to enable quick and easy engagement and disassembly as required by the healthcare professional.



Needle hub pull-out tests commonly assess joint strength in development and production.



The tear strength of device packaging material is a critical parameter in assuring quality in production.

In the case of luer locks, torque assessment should be performed on a low-level torque testing system, with a motorized base plate and a low capacity (e.g. 1.5 Nm) torque transducer. Universal gripping pegs may be used to hold the sample in place, although customized fixtures ensure greater accuracy and repeatability. The most common test involves tightening the luer lock connection between a needle and a fluid-filled syringe to a pre-determined torque, and visually inspecting the joint for leakage. This test is described in international standard ISO 594 - 1/2.

Syringes

Syringes must deliver and extract fluids in a smooth, controlled manner. A syringe plunger that is too easy or hard to actuate, or that stalls and judders on depression will not perform reliably during injection or aspiration.

The efforts required to expel liquid from the syringe, and draw liquid into the syringe, are known as the expression force and aspiration force respectively. These will be determined by a range of variables, including the viscosity of the liquid, the size of the syringe/needle aperture, the 'fit' of the plunger within the syringe barrel and the density of the tissue substrate. The syringe must be developed with the optimum balance of these variables to assure consistency and usability.

International standard ISO 7886 describes a method for determining aspiration and expression forces using a syringe half-filled with water, vertically mounted onto a motorized force testing system. The syringe outlet is connected to a reservoir (open to atmospheric pressure), with the water level aligned to the fill level in the syringe chamber. The piston is held from below by a suitable lower fixture. On initiation, the system pulls the syringe plunger down at a constant rate, drawing fluid into the chamber, and records the aspiration force. The motor is then reversed to record the expression force. Anomalous peaks and troughs in the force profile are monitored to ensure the syringe provides a smooth motion of aspiration and expression.

Other common force tests performed on syringes include chamber stress-cracking to assess compression resistance and disassembly force testing of the rubber plunger from the piston.

Packaging

Needle and syringe packaging must ensure the device remains secure, sterile, and undamaged during transportation and storage, while remaining easily accessible on demand. Force and torque testing in design, production, and processing greatly aids the creation of user-friendly and consistently reliable packaging.

Typical applications include:
Tensile strength, elongation, and tear testing of flexible packaging material (in line with ISO 11607 and EN 869-1 standards)
Peel strength of adhesive sealed needle and syringe packs to qualify 'openability'
Pierce testing of films and foils used on needle blister packs
Co-efficient of friction assessment of packaging material to optimize form-fill-seal machinery settings

Conclusion

There are many useful force and torque testing applications throughout the lifecycle of needle and syringe devices; from forming the needle, joining it to its hub, and packing it in the factory to unwrapping the needle, attaching it to a syringe, and injecting a patient at the hospital. Developers and producers alike should take advantage of these tests as a fast, inexpensive, yet accurate method of assessing the quality, usability, and conformance of their products to international standards.

ONLINE

For additional information on the technologies and products discussed in this article, visit Mecmesin Force & Torque Test Solutions at www.mecmesin.com [1].

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Testing Solutions Online

In June, the *Medical Design Technology* Buyers Guide was delivered in the mail. However, design engineers may be looking for a specific solution when out of convenient reach of the print publication. Therefore, the complete directory is also available online at the magazine's website, www.mdtmag.com, where it is continually updated throughout the year with new companies and services. The following is only a sample of those companies listed on the site ready to address a wide array of the testing needs of medical device manufacturers.

AppTec
2540 Executive Drive
St. Paul, MN 55120
www.apptec-usa.com [3]

Biotest Laboratories Inc.
8990 Springbrook Dr., Suite 100
Minneapolis, MN 55433
www.biotestlabs.com [4]

Bodycote Materials Testing Inc.
7530 Frontage Rd.
Skokie, IL 60077
www.bodycote.com [5]

BSI Management Systems
12110 Sunset Hills Rd., Suite 200
Reston, VA 20190
www.bsiamericas.com/MDTguide [6]

Carl Zeiss IMT Corp.
6250 Sycamore Ln.
Maple Grove, MN 55369
www.zeiss.com/imt [7]

DDL Inc.
10200 Valley View Rd., Suite 101
Eden Prairie, MN 55344
www.testedandproven.com [8]

D.L.S. Electronic Systems Inc.
1250 Peterson Dr.
Wheeling, IL 60090
www.dlsemc.com [9]

Mitutoyo America Corp.
965 Corporate Blvd.
Aurora, IL 60502
www.mitutoyo.com [10]

MTS Systems Corp.
14000 Technology Dr.
Eden Prairie, MN 55344-2290
www.mts.com [11]

Nelson Laboratories Inc.
6280 S Redwood Rd.
Salt Lake City, UT 84123-6600
www.nelsonlabs.com [12]

Underwriters Laboratories Inc.
333 Pfingsten Rd.
Northbrook, IL 60062-2096
www.ul-vip.com [13]

Visit the Buyers Guide online for more information about these companies, as well as to review and research a variety of companies ready and able to fulfill a range of other medical device manufacturing needs.

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