



Numedico[®]
TECHNOLOGIES

Numedico ClickZip Product Range 2023



Providing quality medical supplies globally
from a trusted Australian company.

www.numedico.com

About Numedico[®]

**Focused on safety.
Driven by excellence.
Doing things differently.**

Established in 2016 out of a desire to pursue optimal medtech solutions to challenge the status quo, Numedico is a globally focused medical supplies company based in Australia.

Our solutions include safety syringes for use at home, hospitals and clinics.

We care about our customers and with offices in various global hubs are able to provide excellent customer service and a hassle-free experience.



Drug Delivery Products





Manual Retractable Needle Safety Syringe

Designed using patented technology the Numedico manual retractable needle safety syringe range features an easy-to-use needle retraction mechanism to protect the user and the patient from needlestick injury after injection. Once the needle is safely retracted inside the barrel of the syringe the unique tilting mechanism prevents reuse of the needle.

Satisfying ISO 13485 quality management standards demanded by CE, MHRA, TGA and US FDA, Numedico manual retractable needle syringes are independently tested by NATA approved laboratories to guarantee Numedico's product performance standards are met.

With less sharps waste and a safety mechanism that prevents needlestick injury and reuse. Long-term and other immediate costs are measurably lower and safety benefits increased.

How to use

The below diagram provides a simple step by step process for the operation of the syringe: Draw, Inject, Zip and Snap.



01

Make sure the needle is fixed tight and then use the standard aseptic technique to draw out the medication and fill the syringe. Do not press the plunger to the end. Use the cover to tighten the needle.



02

Inject the medication by fully depressing the plunger to the end of the syringe barrel to engage the locking mechanism. The user will be able to feel and hear a 'CLICK'.



03

'ZIP' the plunger back to retract the needle safely back into the barrel. The needle will tilt to one side, encapsulating the needle in the barrel of the syringe, preventing reuse or needlestick injury.



04

'SNAP' off the plunger at the breaking point. The manual retractable safety syringe is now disabled and cannot be reused. Discard in accordance with your facility's protocol.

Before use



After use



Product range note:

The manual retractable needle safety syringe with a fixed needle is available in sizes 0.5 and 1 ml.

The manual retractable needle safety syringe with a detachable needle is available in sizes 2, 3, 5 and 10 ml with a Luer Lock connection allowing medication to be drawn with an exchangeable needle.

For more details and order enquiries please email: sales.usa@numedico.com

Product Range



Technical Data Sheet

Needle Retractable Safety Syringe

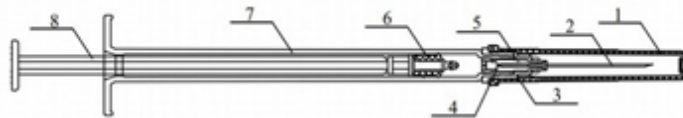


Figure 1 Structure of Needle retractable safety syringe 1ml

Product
Structure

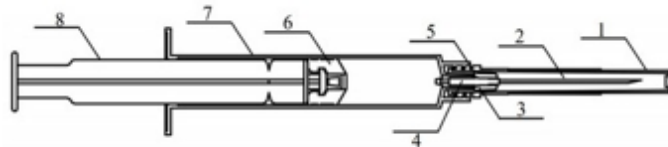


Figure 2 Structure of Needle retractable safety syringe 3ml

| Material | No | Item | Material |
|----------|----|-----------------|---------------------------------------|
| | 1 | Needle cap | PP |
| | 2 | Needle tube | Austenitic stainless steel 304 |
| | 3 | Needle hub | PP |
| | 4 | Retraction part | Acrylonitrile Butadiene Styrene (ABS) |
| | 5 | Seal ring | Silicone |
| | 6 | Piston | Rubber |
| | 7 | Barrel | PP |
| | 8 | Plunger | PP |

| Features | Benefits |
|--------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The barrel incorporates the needle back-stopper | Prevents the syringe disassembling |
| The safety feature is an integral part of the device | No need to 'add-on' safety features, no additional operation required and user-friendly technology |
| The user can hear and feel when the locking mechanism is activated | The user knows when injection has been successfully delivered, increasing the user's confidence Meets NIOSH recommendation for needlestick devices |
| After needle retraction, the plunger is snapped off encapsulating the used needle | Safe disposal after use and further prevention of reuse or needlestick injury |
| Break away plunger | Prevents reuse |
| Full compliance with ISO 13485 USFDA EU MDD/MDR | Meets international standards for medical devices |
| Highest quality Japanese designed stainless steel cannulas | Sharp needle to reduce pain for patient |
| Latex free | Eliminates latex sensitivities |
| No leakage | Avoids contamination |
| No gap - minimal dead space | Reduced viral survival |
| Active-retractable needle technology – manual retraction | Increased user control |
| After the injection is given, the user can retract the needle before of after removing the needle from the patient | Reduce needle exposure Increase users control and safety |
| No change to injection technique | No or minimal training required – simple to use |
| When retracted after use, the needle tilts to one side into the syringe barrel | Encapsulating the needle in the barrel of the syringe increases safety, reduces risk of needlestick injury, prevents reuse of needle and reduces need for sharps container |

Standards

| | |
|----------|---------------------------------------------------------------------------------------------------------------------------------|
| Standard | 93/42/EEC+2007/4 7/EC: 2007 14th, June, 1993, Medical Device Directive 93/42 / EEC of the European Community |
| | EN ISO 13485 2016 Medical devices. Quality management system. Requirements for regulatory |
| | ISO 14644-1: 2015 Clean room and associated control environment. |
| | EN ISO 14971: 2012 Medical devices - Application of medical device management risk |
| | EN ISO 10993-1:2009/ AC:2010: 2010 Biological evaluation of medical devices. |
| | EN 1041: 2008 Information supplied by the manufacturer of medical devices |
| | EN ISO 15223-1: 2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied. |
| | EN ISO 10993-4: 2017 Biological evaluation of medical devices. |
| | EN ISO 10993-5: 2009 Biological evaluation of medical devices. |
| | EN ISO 10993-10: 2013 Biological evaluation of medical devices. |
| | EN ISO 10993-11: 2009 Biological evaluation of medical devices. |
| | EN ISO 10993-7: 2008 Biological evaluation of medical devices |
| | ISO 11135-1: 2014 Sterilization of health care products. |
| | EN ISO 11138-2: 2017 Sterilization of health care products. |
| | EN ISO 11737-1: 2009 Sterilization of medical devices - Microbiological methods. |
| | EN ISO 11737-2: 2009 Sterilization of medical devices - Microbiological methods. |
| | ISO 11607-1: 2019 Packaging for terminally sterilized medical devices. |
| | ISO 11607-2: 2019 Packaging for terminally sterilized medical devices. |
| | EN ISO 14155: 2011 Clinical investigation of medical devices for human subjects. |

Product Range

| Description | Needle Gauge | Needle Length | QTY per inner | QTY per carton |
|------------------------------------------------------------------------------|--------------|---------------|---------------|----------------|
| 100U ClickZip Slimline Manual Retractable Safety Insulin Syringe with needle | 30 | 0.5 | 100 | 2400 |
| 0.5ml ClickZip Slimline Manual Retractable Safety Syringe with needle | 23 | 1" | * | * |
| 0.5ml ClickZip Slimline Manual Retractable Safety Syringe with needle | 25 | 5/8" | 100 | 2400 |
| 0.5ml ClickZip Needle Retractable Safety Syringe with needle | 25 | 1" | * | * |
| 1ml ClickZip Slimline Manual Retractable Safety Syringe with needle | 25 | 5/8" 1 | 100 | 2400 |
| 3ml ClickZip Needle Retractable Safety Syringe with <u>needle</u> | 25 | 1" | * | * |
| 5ml ClickZip Slimline Manual Retractable Safety Syringe with needle | 23 | 1.5" | 100 | 900 |
| 5ml ClickZip Slimline Manual Retractable Safety Syringe with needle | 25 | 1.5" | 100 | 900 |

Standards

| | |
|----------|-----------------------------------------------------------------------------------------------------------------------------------|
| Standard | EN 62366-1: 2015 Medical devices - Application of usability engineering to medical devices. |
| | EN 20594-1: 1993/A1:1997: 1997 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment. |
| | ISO 7864: 2016 Sterile hypodermic needles for single use. |
| | ISO 7886-1: 2017 Sterile hypodermic syringes for single use. |
| | ISO 7886-4: 2018 Sterile hypodermic syringes for single use. |
| | MEDDEV 2.7.1 Rev 4 2016 Clinical evaluation: a guide for manufacturers and notified body |
| | MEDDEV 2.12-1 rev 8 2013 Guidelines on a medical devices vigilance system |
| | MEDDEV 2.12-2 Rev 2 2012 Post Market Clinical Follow-up studies |
| | MEDDEV 2.5/10 2012 Guideline for Authorized Representatives |
| | MEDDEV 2.5/5 Rev.3 1998 Conformity assessment procedure - Translation procedure |
| | CE0197 |
| | FDA 510K |



Numedico®
TECHNOLOGIES

**Preventing
bloodborne
disease is
our priority**





Our future focus is driven by a desire to improve healthcare and to find the best and safest solutions to suit our customer's needs now and tomorrow.

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