

Needles – More than just a piece of metal

Needles are some of the most common products in healthcare. They are used for minimally invasive procedures such as aspiration, blood collection but also administration of medication. They should be safe, sterile with a long shelf-life, sharp, intuitive and easy to use. Medical devices that have direct contact with skin are ideally not made with latex and should be available in various sizes and needle gauges for patient and user convenience.

The user must then choose the appropriate needle size and gauge based on the size of the patient's vein, physical status of the patient, tube volume, amount of blood drawn or substance to be administered. To be able to do so, it's beneficial to know all the options.

DESIGN

Needle Gauge

Have you ever wondered about the word *gauge* (G)? Why is a 10G needle (3.4mm outer diameter) thicker than a 20G needle (0.9mm outer diameter) and why do the numbers not correlate with the millimetres?

Gauge is pronounced /*geɪdʒ*/ and comes from the French word 'jauge', which means '*result of measurement*'. The history is very long and complex, but it was already mentioned in 13th century documents and then used by iron wire drawers in the 19th century England who expressed the diameter of their steel wires in *wire gauges*: the amount by which wires could be reduced by each draw through a conical hole. A manufacturer usually had a test wire to check if the size was suitable for the customer.

With increasing industrialisation, also the need for standardisation increased and manufacturers started to express the diameter of their steel wires in fractions of an inch.¹

Birmingham Wire Gauge formula from 1856²:
 Thickness in inches = $0.300 \times 0.897^{(\text{gauge number}-1)}$

There have been a lot of modifications since these times, but one thing remained: the higher the gauge number, the thinner the needle.

Nowadays, international standards provide exact specifications. ISO 6009³ is one of them and regulates colour coding for easy identification of hypodermic needle gauges, for example:

20G (yellow),
 21G (deep green) or
 22G (black)

It allows users to quickly choose suitable needle sizes by gauge, rather than by its actual metric size.



Figure 1: 21G VACUETTE® VISIO PLUS Needle with green translucent cap

Stainless Steel

The needle cannula is usually made of stainless-steel with the number **SUS 304** (ISO number 4301-304-00-1). The chemical composition is (%) C 0.07, Si 1.00, Mn 2.00, P 0.045, **S 0.03**, Cr 17.5-19.5, N 0.1 and Ni 8.0 -10.5 as defined in ISO 15510⁴. The standard ISO 9626⁵ sets out the technical requirements for the stainless steel used for the manufacture.

Nickel

As described above, there is a relatively high level of nickel to be found in stainless-steel as it is also naturally present in the environment.

In a French study, the behaviour of SUS 304 regarding contact allergy was examined. The result was that non-resulfurized stainless steel such as SUS 304 with sulphur content around 0.03% could be used without any problem in contact with the skin. Resulfurized grades with S > 0.1% (e.g. SUS 303) would elicit Ni dermatitis in a small percentage of cases.⁶ Caution is still advised, if a patient is allergic as “allergies are on the rise over the recent years”.⁷

Needle Wall

Amongst other properties, the needle wall must have a smooth surface and be free from visual defects or particles. The steel tubing should be straight, round and is available in 4 different versions: regular-walled, thin-walled and some gauges also extra-thin walled and ultra-thin walled. The international product standard ISO 9626 sets out the dimensions of the steel tubing by providing the allowed minimum and maximum outer diameter as well as the minimum inner diameter for most gauge and needle wall types.

Although the gauge (outer diameter) remains the same, thinner needle walls have a larger inner diameter, which can have an impact on the flow rate and administration time of medication.

In an internal evaluation⁸, regular and thin-walled cannulas were compared regarding their flow rates (mL/min with water). The main differences were as follows:

<u>Gauge</u>	<u>Δ thin wall - regular wall</u>
20G	7.7 mL/min
21G	2.9 mL/min
22G	0.11 mL/min

Needles with extra-thin walls may, for example, be beneficial for blood tests like thrombocyte function, where regular small gauged needles ($\leq 25G$) would otherwise lead to platelet activation or haemolysis.⁹

So, why are thin or extra thin wall dimensions not always used for the manufacture of this type of products? The thinner walled a needle is, the more complex and involved the manufacturing process is, which results in the products being more expensive to produce. The industry always aims to find an optimal balance between the best product at an affordable price. Also, thinner walled needles have a higher dead volume compared to the corresponding regular walled needles.

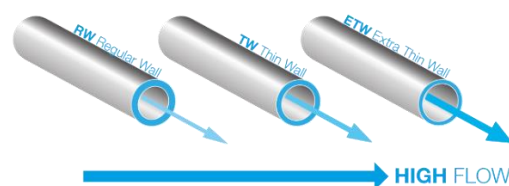


Figure 2: 3 different needle wall types

Siliconization

Needle walls also have a slight silicone oil coating on the outside to minimize penetration force and discomfort when the needle enters the tissue. The non-patient end of blood collection needles and luer adapters, which is usually covered by a rubber sleeve, are also siliconized to allow the proper retraction of the sleeve. Only a fully retracted rubber sleeve prevents leakage after removal of a blood collection tube to avoid blood spillage.

Needle Bevel

The needle bevel must allow for easy cutting of the tissue. The force which is needed for the puncture depends on the geometry of the cutting-edge. The maximum sharpness is achieved with a very small angle (less than 15°) similar to the ones on razor blades or scalpels.¹⁰ The tip is therefore very thin and fragile and must not touch the needle cap during its removal. A straight twist-pull movement is usually advised. Upon use, the needle tip punctures the skin, while the 2 sides of the bevel slice through the tissue until the desired position is achieved. Most of the needles therefore have a so called 3-bevel cut.



Figure 3: 3-bevelled needle tip

SAFETY

It is now clear that one of the most common products in healthcare also poses a certain risk for even the most experienced user. The majority of needlestick injuries however is preventable using safety products.

Education, training and awareness-raising are necessary to reduce these risks associated with blood and body fluid exposure. In the US, the Needlestick Safety and Prevention Act got effective on April 18, 2001 and in Europe the EU Council Directive 2010/32/EU on the prevention of sharps injuries in the hospital and healthcare sector was passed to protect healthcare workers from accidental exposure. It had to be implemented by May 11, 2013 at the latest.

Selection criteria of safety products include:

- 1) the safety mechanism should be an integral part of the used system, meaning a safety engineered component (i.e. shield) should already be present on the needle or syringe or blood collection holder prior to use;
- 2) the device must be intuitive,
- 3) the device must be easy to use;
- 4) the device should require little change of technique, and
- 5) the safety mechanism should not be reversible once activated.¹¹

Are needle devices latex free?

You may have read the wording: “[...] not made with natural rubber latex.” But what does that mean?

Synthetic polymer sleeves placed on the back-end of blood collection needles, winged needle tubings or wings are ideally not made with latex and some of these products were previously labelled as “latex-free”. The US FDA however stated that this wasn’t accurate and would be misleading as there is no test available that can screen for the absence of allergens on the product or packaging. Hence the US FDA

suggested the wording as mentioned before “[...] for scientifically accurate labeling that can be used by manufacturers who wish to convey that natural rubber latex was not used as a material in the manufacture of a medical product, medical product container, or medical product packaging [...]”¹²

If a product is made with any form of latex or dry natural rubber that could cause allergic reactions, the information must be on the labelling.



Figure 4: Latex symbol on products made with latex or dry natural rubber as per ISO 15223-1¹³

Do needle devices contain DEHP?

DEHP is an abbreviation for *di(2-ethylhexyl) phthalate*. It is a chemical that is added to plastics to make them flexible.¹⁴ DEHP is also widely used as a plasticiser in polymer products such as PVC. PVC is used in toys, flooring, cables but also medical products like *winged needles*, artificial heart valves, syringes, catheters and blood bags.

There have been risk reports from official agencies because of concerns with regards to toxicity of its metabolites to kidneys and reproductive organs on repeated exposure or when undergoing long-term transfusions. Leaching of DEHP, for instance, is possible during storage of a product or when it is heated or in contact with certain media. Intravenous

exposure is possible during infusions with PVC equipment and especially infants, children and vulnerable patients (e.g. seriously ill, old, pregnant) are at risk.¹⁵

Most of the available products today are *non-DEHP*. i.e. not made with DEHP. There are other plasticisers available such as TOTM (trioctyltrimellitate) which has a low release rate, shows hardly any toxicity in in-vitro studies with incubated hepatocytes and is therefore recommended as an alternative to DEHP.¹⁶



Figure 5: symbol for products which contain DEHP. Requirement as per EN 15986

Does sterile also mean pyrogen free?

No. The word pyrogen comes from the Greek word *pyros* which means *fire*.

With the invention of the hypodermic needle, infusions had become common practice by the beginning of the 19th century. In many cases however, even sterile procedures were often followed by severe fevers of unknown origin. These fevers were suspected to occur after infusion of even sterile solutions and therefore simply called “saline fever”, “injection fever” or “distilled water fever”.¹⁷

Today we know that the real source of these fevers were pyrogens, untouched by sterilisation, and that there are many different types. Exogenous substances of microbial origin

are for instance endotoxins (LPS), exotoxins, fungi and parasites. But also non-microbial exogenous substances can cause fevers. Examples are culture media components, cell breakdown products, plastic particles, steroids or dust.¹⁸

It is rather difficult to remove pyrogens from sterile needles, therefore the goal is to keep the product free from them. The first step in the production is to avoid the presence of any

foreign matter, especially gram-negative bacteria, the source of endotoxins.

Another measurement is testing for pyrogens. A common method, that doesn't involve rabbits, is the Limulus Amoebocyte Lysate (LAL) assay, which has been widely used for the detection of endotoxins in quality control of medical devices.

If the pyrogen level is below the allowed limit, the medical device can be labelled as *non-pyrogenic*.¹⁹

FURTHER INFORMATION

For more information, see product overview in catalogue number 980042 and all respective Instructions for Use and brochures on https://www.gbo.com/de_AT/know-how-services/download-center.html

[gbo.com](https://www.gbo.com) > [Know-How & Services](#) > [Download Center](#)

Legal requirements - according to medical device regulations all necessary information, which is required for a safe application of the device needs to be provided by the manufacturer. Therefore, please refer to the current valid instructions for use!

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