

# Haemodialysis plastic cannulae - a possible alternative to traditional metal needles?

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## ABSTRACT

**Background:** Haemodialysis plastic cannulae for arteriovenous fistulae (AVF) have been used for many years in Japan and recently this technique was introduced in Australia.

**Objectives:** Find answers to the following questions:

What are the pros and cons of plastic cannulae versus traditional metal needles for AVF and arteriovenous graft (AVG)? Is the use of plastic cannulae instead of traditional metal needles an option for European dialysis units as well? If it is an option, for which patients should plastic cannulae be used?

**Methods:** Literature search via PubMed and Google.

**Results and conclusion:** Due to the characteristics of plastic cannulae, they seem to be well suited for restless patients, patients with unpredictable behaviour, children, and patients who are allergic to metal. However, the evidence base provided by studies on the use of cannulae is currently weak. More controlled randomised studies are needed.

**Keywords:** Fistula cannulae, Fistula needles, Vascular access cannulation

## Background

In haemodialysis, arteriovenous fistula (AVF) cannulation can be performed via rope ladder, buttonhole or area technique, with the latter being the least favoured while, for arteriovenous graft (AVG) the preferred cannulation technique is rope ladder. To date, no strong scientific evidence supporting the use of buttonhole for AVG has yet been generated.

A literature search did not reveal any detailed data on the type of cannulation device which is used to puncture the AVF/AVG.

Sharp metal needles can be used and blunted metal needles are also available for the buttonhole technique. The metal needles are usually siliconised. Alternatively, one can use haemodialysis plastic cannulae, which are inserted into the vessel using an introducer metal needle which is removed after the cannula is pushed into the vessel. Therefore, during the dialysis treatment only the plastic cannulae and not the introducers stay within the vessel.

In Europe traditional siliconised metal needles are the most frequently used, whereas in Japan – according to Grainer (1) and Du Toit (2) – haemodialysis plastic cannulae have been available for many years and most vascular access cannulations are performed using cannulae. The use of plastic cannulae for AVF has also recently been introduced in Australia, and initial results have been reported at the Renal Week of the Renal Society of Australia in August 2014 (3). The implementation of the new cannulation technique with plastic cannulae in the Australian Barwon Health Renal Department is reported upon in this issue (4).

Can the use of plastic cannulae be an alternative to traditional metal needles for AVF cannulation in the European dialysis centres? And if yes, for which patients?

A basic overview of traditional fistula needles and plastic cannulae for haemodialysis characteristics will help to create a better understanding of the advantages and disadvantages of both products.

## Characteristics of metal needles and plastic cannulae

The effective blood flow is influenced by the dimension of the needle or plastic cannula and the status of the arteriovenous fistula. Metal needles and plastic cannulae are available in different inner diameters and different lengths, both influencing the effective blood flow. The larger the inner diameter and the shorter the needle or cannula, the higher the blood flow rates that can be attained.

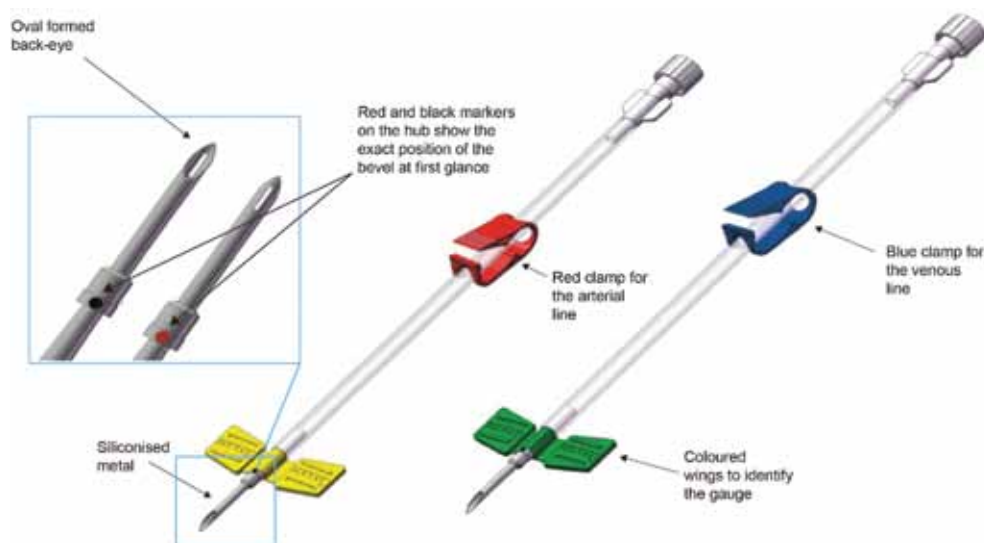
Figure 1 demonstrates the principle design of traditional fistula needles. Each manufacturer has their own system to

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**Fig. 1** - Features of traditional dialysis needles. Picture with the courtesy of Bionic Medizintechnik GmbH, Friedrichsdorf, Germany.

**TABLE I** - Available dimensions of metal needles for haemodialysis (providers are listed in Table II)

Needle gauge	Needle length
14 G	20, 25 mm
15 G	15, 20, 25, 32 mm
16 G	15, 20, 25 mm
17 G	15, 20, 25 mm
18 G	20 mm

code the different dimensions by using different coloured wings. The wings make it easier for the needles to grip and they facilitate accurate puncturing.

Various authors propose using both needles with back-eye (5); or at least in the arterial needle (6). The assumption is that a back-eye in the needle assures optimal blood flow (5, 6) and minimises the risk of suction of the needle to the vessel wall (6). However, these effects are not proven by clinical data.

Coloured dots indicate the bevel orientation (up or down) in the vessel during cannulation and treatment.

Most of the time, needles are siliconized, which makes it easier for the needle to slide into the vessel during puncturing and out during removal. Furthermore, the silicon coat improves the biocompatibility of the metal needles. Fistula needles are sterilised either by irradiation or by ethylene oxide (ETO).

In Europe, venous and arterial metal needles are available in the dimensions listed in Table I. In addition, single needles are available for related treatment modality.

Plastic cannulae are considered to be highly biocompatible. Each plastic cannula is delivered together with an inner metal needle (without a hole) which serves as an introducer for the cannula into the vessel. As the inner diameter of a cannula is smaller than the outer diameter, the introducer also has a smaller diameter than the cannula. Some cannulae are described as having a 2-gauge difference between the inner and outer diameter (see providers of plastic cannula in Table II).

**TABLE II** - Needle and cannula providers

Providers	Product link / reference
Bionic	<a href="http://www.vascular-access.com/wp-content/uploads/sites/4/2015/12/pdf-english-fistula-needles.pdf">http://www.vascular-access.com/wp-content/uploads/sites/4/2015/12/pdf-english-fistula-needles.pdf</a>
Gambro	<a href="http://www.gambro.com/PageFiles/7468/HCEN5866_1_Gambro%20Fistula%20Needles.pdf?epslanguage=en">http://www.gambro.com/PageFiles/7468/HCEN5866_1_Gambro%20Fistula%20Needles.pdf?epslanguage=en</a> <a href="http://www.gambro.com/PageFiles/6028/Gambro%20Supercath%20Needle,%20Produktatablad.pdf?epslanguage=en">http://www.gambro.com/PageFiles/6028/Gambro%20Supercath%20Needle,%20Produktatablad.pdf?epslanguage=en</a>
Nipro	<a href="http://www.nipro-europegroupcompanies.com/product/standard/#post-210">http://www.nipro-europegroupcompanies.com/product/standard/#post-210</a>
Medikit	<a href="http://www.medikit.co.jp/english/product/pdf/CLS_brochure.pdf">http://www.medikit.co.jp/english/product/pdf/CLS_brochure.pdf</a>

**TABLE III** - Available dimensions of plastic cannulae (providers are listed in Table II)

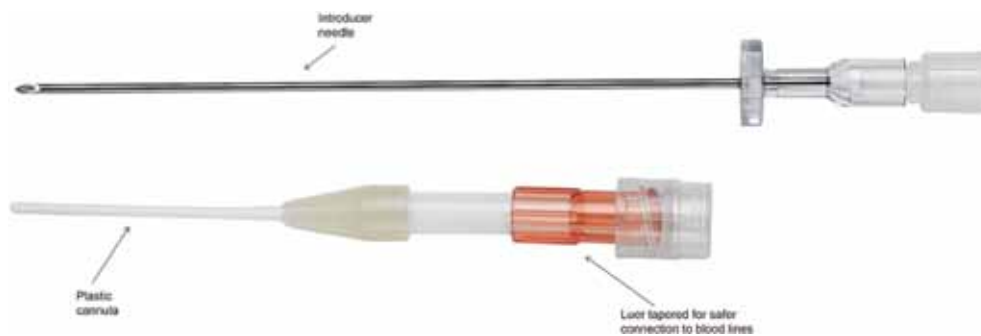
Cannula gauge	Cannula length
14 G	25, 32, 38 mm
15 G	25, 32, 38 mm
16 G	25, 32, 33, 38 mm
17 G	25, 32, 33, 38 mm
18 G	25 mm

Often, the listed size of plastic cannulae refers to the dimensions of the introducer needle (7) or the inner diameter of the plastic cannula.

Some providers of plastic cannulae describe them as having side holes. It is stated that these side holes may improve blood flow and prevent the vessel wall from occluding the cannula (8). The cannulae are Luer tapered for safer connections with blood lines. Figure 2 shows the features of plastic cannulae.

In Europe, plastic cannulae are available in the dimensions listed in Table III.





**Fig. 2** - Features of plastic cannulae. Picture with the courtesy of Nipro Europe NV.

Blood flow and pressure characteristics of plastic cannulae seem to be reliable. Avitable and Stephenson (9) studied (in vitro) flow and pressure results of haemodialysis plastic cannulae (Argyle Fistula Cannulae, which are not yet available in Europe). They found out that the 15-gauge cannulae allowed adequate flow rates without exceeding arterial or venous pressure of  $\pm 140$  mmHg, respectively, at a flow rate of 300 mL/min; while the 17-gauge cannulae already reached these pressure values at a flow rate of 250 mL/min.

Grainer et al (10) observed desirable flow parameters in 83 dialysis sessions, using mainly 15-gauge plastic cannulae. In 87% of these sessions the effective blood flows were  $\geq 300$  mL/min and in the remaining sessions between 230 and 280 mL/min. The median arterial pressure was  $-140$  (range:  $-40$  to  $-200$ ) mmHg and the median venous pressure was 130 (range 100 to 200) mmHg.

### Costs of metal needles and plastic cannulae

In Europe, a plastic cannula with introducer needle costs between EUR 1.20 and EUR 1.40 more than a metal needle. Since we need two plastic cannulae per session for a patient and the patient has three sessions a week, it results in additional costs between EUR 7.20 and EUR 8.40 per week or between EUR 374.40 and EUR 436.80 per year.

### Cannulation techniques with metal needles and with plastic cannulae

Different aspects, such as selecting the puncture sites using rope ladder, area or buttonhole technique (the latter only for AVF) and arterial needle direction, may influence AVF and AVG survival (11). Not all cannulation techniques with traditional metal needles are explained in detail in this paper as they are well known and often discussed in other publications.

The insertion of plastic cannulae into the AVF differs considerably from the procedure performed with metal needles. Plastic cannulae are inserted into the sites of the AVF via an introducer needle. The tip of the introducer punctures the skin first and then the vessel. The cannula has to be introduced into the vessel until the bevel of the introducer is completely inside the vessel. The cannula slides into the vessel and the introducer is removed simultaneously (2, 4). Unlike puncturing with traditional metal needles, the cannulator has less control on the success of the puncture, as the blood flashback does not pulsate (4).

The plastic cannulae are longer than traditional metal needles. The cannulator therefore has to hold them further back from the puncture site compared to a traditional needle (1). Furthermore, they have no wings to hold on (4). During the insertion process, blood cannot spill out from the cannula due to the presence of stop valves (1, 4).

Using cannulae, only the plastic component stays in the vessel during the dialysis session, whereas with traditional fistula needles, the metal needles are in situ during the complete dialysis session.

### Literature review

#### *Injury of the vessel during cannulation*

When using a plastic cannula instead of a traditional fistula needle, the metal introducer has a smaller size than the corresponding plastic cannula and therefore causes smaller puncturing holes. Smith and Schoch (4) observed that miscannulations with plastic cannulae “were not as disastrous as with metal needles”. They assumed that the smaller needle tip of the introducer may potentially lead to minimal haematoma formation, which allowed additional cannulation attempts.

However, their studies also showed that cannulation with cannulae is more difficult than with traditional metal needles.

#### *Needle infiltration during cannulation and dialysis*

When the AVF is cannulated by traditional metal needles, sharp needles can harm the vessel or even infiltrate into the vessel wall during the cannulation process or during dialysis treatment, for example when patients move their arm.

Infiltration is when the needle tip extends out of the vessel wall into the surrounding tissue (2). As a consequence, blood leaks into the surrounding area and the needle has to be removed. Haematomas and – in the medium/long term – thrombosis may develop. According to Lee et al (12), needle infiltration into the vessel wall is a common risk in dialysis patients treated via AVF.

As the metal needles stay in situ during the dialysis session there is always a risk of damaging the internal vessel wall or of generating infiltration when patients move or bend their vascular access arm. While with cannulae, because of the softer and blunted material, the risk of intra-dialysis vessel damage or infiltration may be reduced. The author Grainer (1) reported 120 successful cannulations with plastic cannulae in their clinical setting, mainly carried out under ultrasound guidance.

From his cannulation experiences with needles and cannulae, Grainer concluded (without showing concrete detailed data) that, in comparison with traditional needles, plastic cannulae could:

- Show no initial advantages towards infiltration during cannulation of immature AVF.
- Avoid or reduce mid-treatment infiltration (relatively common when using metal needles) of premature fistulae.

In the case of an AVF already having haematoma from previous treatments but needing access for dialysis, Grainer (1) preferred to use plastic cannulae instead of metal needles.

A retrospective study carried out by Letachowicz et al (13) in a Polish dialysis unit compared the development of haematoma in 20 patients punctured with plastic cannula (17-gauge) with 19 patients punctured with metal needles (16-gauge). All patients had a newly created AVF and cannulations were performed within the first 30 days after creation.

Results showed that 5 haematomas occurred during 299 cannulations with plastic cannulae and 12 haematomas during 250 cannulations with metal needles ( $p = 0.035$ ).

There was no statistically significant difference in the proportion of patients who developed haematomas between both groups. (5 [25%] patients of the plastic cannula group and 6 [31.6%] patients of the metal needle group developed haematomas [ $p = 0.648$ ]). However, the number of haematomas per patient was lower in the plastic cannula group.

As only a small number of patients were studied in a non-randomised way, the results give only initial hints that plastic cannulae could cause fewer haematomas.

Prospective randomised controlled studies on needle infiltration or the development of haematoma are needed. Studies should also take into account haemodialysis adequacy parameters that should be comparable between patients using plastic cannulae versus patients using metal needles.

### **Cannulation of newly created AVF**

The above-mentioned study by Letachowicz et al (13) demonstrated successful cannulations with plastic cannulae in newly created AVF, without a negative influence on access survival. The authors stated that the study is limited by the small sample groups, not being randomised and by not including ultrasound-guided cannulations.

In an Australian renal department, the insertion of plastic cannula into AVF was introduced during an extensive training period. This training included performing at least 10 successful cannulations on a practice training arm, followed by three supervised, successful cannulation sessions on mature AVFs. First results are published by Smith and Schoch in this issue (4). Successful cannulations were carried out on 10 new patients with an AVF and on 9 patients who originally started haemodialysis via a CVC but later had an AVF created. They assumed that the successful use of plastic cannulae for haemodialysis patients with newly created AVF might have contributed to the increasing incidence of patients using AVF or AVG as first vascular access for dialysis in their unit.

### **Cannulation of deep AVF**

The longest available traditional fistula needle has a length of 32 mm. Plastic cannulae are available with a maximum length of 38 mm. This length makes it possible to cannulate difficult AVFs which are located deeper, as in obese patients, without the need for surgical intervention to reposition the fistula vessel closer to the skin surface (1).

### **Increased possible areas of AVF cannulation with plastic cannulae**

Du Toit reported from her informative visit in Japan that they were able to cannulate larger regions of the AVF with plastic cannulae; for example, they were able to cannulate near to the elbow crease or close to bends (2). In his practical work, Grainer (1) had at least three incidents of reduced puncture zones caused by mid-dialysis treatment infiltration from steel needles where re-needling was required. It was possible to cannulate into the cephalic vein in the cubital fossa with a plastic cannula.

### **Pain during cannulation with plastic cannulae versus metal needles**

In a prospective, non-randomised study, 14 patients were surveyed for pain during cannulation and needle or cannula withdrawal in 12 dialysis sessions using metal needles and 12 sessions using plastic cannulae (14). In this study, the same patient was case and control. The evaluation of the validated visual analogue scale revealed less pain if patients were cannulated with plastic cannulae instead of metal needles. This difference in pain was not found with the Short-Form McGill Pain Questionnaire (14). On the contrary, Ocaña et al (15) reported that patients found plastic cannula insertion slightly more painful than needle puncturing, but this might be due to lack of experience in cannula insertion.

### **Needle or plastic cannula for nocturnal dialysis**

Literature describing the type of products to be used to cannulate vascular access in intensive dialysis (including nocturnal dialysis) is rare.

Pierratos reported from an early nocturnal Canadian haemodialysis programme that they used plastic cannulae with the buttonhole technique for AVF cannulation (16). In a later publication he stated (17) that in 33 patients on nocturnal haemodialysis with AVF they initially used plastic cannulae and later used metal needles (17) for buttonhole cannulation. The author does not explain within the publication why the cannulation device was changed.

An Australian nocturnal haemodialysis programme (published 2012) described how, in accordance with the early work of Pierratos, they initially used plastic cannulae but found them harder to insert and therefore preferred to use blunted metal needles (18) with the buttonhole technique.

Faratro et al (19) stated that "the use of sharp fistula needles for nocturnal dialysis is not preferred due to the potential for needle infiltration during the treatment".

**TABLE IV** - Assumed pros and cons of metal needle versus plastic cannula usage for arteriovenous fistulae cannulation

	Metal needle usage		Plastic cannula usage	
	Pros	Cons	Pros	Cons
Cannulation	Easier cannulation technique (most renal nurses are mainly used to this technique)  Possibly lower frequency of miscannulations (this may depend partly on the training experience of the cannulator)	The larger metal needle tip may cause more severe vessel injury or infiltration  Higher risk of needle infiltration during taping  Limited areas of AVF cannulation	The smaller introducer needle tip may cause less severe vessel injury or infiltration  Less needle infiltration during taping  An option for deep AVF cannulation  Increased possible areas of AVF cannulation	Difficult insertion technique    Because of the complicated cannulation technique, miscannulations can occur (possibly dependent on the degree of training of the cannulator)
Treatment		Higher risk of mid-treatment needle infiltration  Movements of the limbs during treatment increase the risk of vessel damage	Less mid-treatment needle infiltration  Comfortable, in spite of patients' arm movements during the dialysis session	
Treatment end		Higher risk of needle infiltration during removal of the tapes	Less risk of needle infiltration during removal of the tapes	
Costs	Lower direct costs		Higher direct costs	

For nocturnal haemodialysis the authors proposed:

- the use of plastic cannulae in the case of rope ladder cannulation of the AVF;
- or the buttonhole technique with plastic cannulae according to a special protocol which is available from "the International Society of Hemodialysis (ISHD)" (20);
- or the buttonhole technique with blunt metal needles.

#### **Potential risk of cannulation errors with plastic cannulae during the implementation phase**

The insertion technique for plastic cannula while puncturing an AVF is different compared to that for traditional metal needles. The cannulator has to hold the cannula further back from the AVF, as the cannula has a longer hub. Therefore, any movement by the cannulator is transferred more strongly to the tip of the introducer into the vessel (1). Also, plastic cannulae with introducers do not have wings like fistula needles and are therefore more difficult to hold.

According to an experienced cannulator, a common problem is that cannulators may not have advanced the introducer far enough into the vessel before advancing the cannula, therefore the cannula cannot enter the vessel lumen (1). As the cannulator cannot manipulate the cannula once the introducer is removed, unsuccessful cannulations can occur (21). Health-care personnel need guided training in order to use this procedure properly (4).

When this insertion technique was introduced in an Australian renal department they needed three times as

long for training (18 months instead of 6 months) of the staff (40 persons) than planned (4). At first, cannulation errors in their unit did not decrease; they assumed this was due to inexperience of the cannulators.

#### **Taping and removing the tapes**

Du Toit (2) mentions that plastic cannulae do not have the same potential as sharp needle tips to injure the vessel wall when, during fixation or removal of the tapes, pressure might be transferred to the needle or cannula.

#### **Pros and cons of both cannulation devices and resulting indications for usage**

The assumed pros and cons of both metal needles and plastic cannulae are listed in Table IV. However, the possible advantage of a decreased risk of needle infiltration during cannulation and dialysis due to the use of plastic cannulae instead of metal needles needs to be confirmed by a randomised controlled study.

In view of the assumed pros and cons of needles or plastic cannulae for AVF/AVG cannulation, the question is which product should be used for which patient? There is a lack of studies with an adequate evidence level for plastic cannulae usage. However, neither do we have evidence for the usage of metal needles.

Common sense suggests that blunt plastic cannulae inside the VA are less likely to damage or infiltrate the vessels during the dialysis treatment than sharp needles.

**TABLE V** - Possible indications for plastic cannula usage

Indications
Restless patients
Patients who are not accountable for not moving their arms during the treatment
Children
Patients on nocturnal or long dialysis
Patients who are allergic to metal

Therefore, if future studies demonstrate the reduction of cannulation and mid-treatment infiltration of the vascular access, it is reasonable to propose the use of plastic cannulae in patients who are not accountable for not moving their vascular access arm during the entire dialysis session, such as children, or restless or psychologically unstable patients with unpredictable behaviour.

Furthermore, plastic cannulae may be advantageous and more comfortable for people on nocturnal dialysis, as it is hard to keep the vascular access arm still during a session longer than 5 hours or while sleeping. Although cannulae have a lower risk of needle infiltration during treatments, we know that in some nocturnal haemodialysis programmes, AVF cannulation (17, 18) was initially performed using plastic cannulae and later on used metal needles (see above). Reasons for this change have not always been given, but one reason mentioned by an author (18) was the difficult plastic cannula insertion technique.

Faratro et al (19) also propose the use of plastic cannulae in patients with metal allergy; this seems reasonable as during the treatment only the plastic cannula and not the siliconised metal needle stays in situ.

Table V summarises populations which could benefit from plastic cannula usage. One limiting or challenging factor for the implementation of plastic cannula for AVF/AVG might be the more complex insertion method.

However, cannula insertion should be done by experienced cannulators to avoid unsuccessful cannulations. If the usage of plastic cannulae is to be introduced on a larger scale in Europe, intensive training has to be provided in accordance with appropriate protocols.

Smith and Schoch observed (4) that novice renal nurses with a background of peripheral cannulation in general wards found it relatively easy to learn to insert plastic cannulae into an AVF. By contrast, for renal nurses who had been puncturing with metal needles for years, it was very challenging to learn this new technique. However, once nurses expert in the use of plastic cannulae are available, these nurses should function either multipliers or trainers.

In the event that plastic cannula usage becomes an option in Europe, patients who could benefit need to be well informed about both possibilities: metal needles or plastic cannulae. The well-informed patient should decide. Whether or not it becomes an option also depends on costs. Plastic cannulae cause more direct costs than metal

needles. On the other hand, the use of plastic cannulae may result in less vessel damage, infiltration, haematoma and, in the long term, less thrombosis and stenosis of AVFs. This could improve AVF survival and reduce hospitalisations. All these aspects must be taken into account in a cost-benefit analysis.

## Conclusions

The main advantage of plastic cannulae versus metal needles for AVF cannulation seems to be the reduced risk of internal vessel wall damage or needle infiltration during the dialysis session, during taping or removing of the tapes. This reduction of risk seems very plausible due to the difference in material between sharp needles and plastic cannulae, but the reduced needle infiltration should at least be confirmed by controlled randomised trials. A cost-benefit analysis is also needed, as the use of plastic cannulae is more cost intensive.

In the event that the innovative technique “cannulating the AVF with plastic cannula” becomes more common, e.g., in restless patients, children, patients on long dialysis sessions or patients with metal allergy, the cannulators for this technique need appropriate training, as the insertion of the cannula is different from puncturing with needles.

Meanwhile, the medical device industry should improve plastic cannula design to make cannulation easier to perform. Customers' experience and clinical data collection analysis could be used as a basis for such improvement.

The era of big data has arrived, but the practice of advanced analytics is also grounded in years of clinical research and scientific application. Data collection and analysis can be a critical tool for realising improvements in yield in which process complexity and process variability restraints are present. Indeed, industries that successfully develop their capabilities in conducting quantitative and qualitative assessments can set themselves up as golden providers for clinical environments.

## Disclosures

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