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### SAMED position on Medical Device Company Representatives in the Clinical Environment

The South African Medical Device Industry Association (SAMED) represents providers of medical devices and equipment supplied to both the private and public hospitals, clinics and healthcare service providers in South Africa. Our member companies portfolio of products include capital equipment; surgical implants; disposable and consumable medical devices, combination products and In Vitro Diagnostics.

SAMED is committed to the development of a sustainable medical device industry by responsibly improving patient access to innovative health technology

It has come to the attention of SAMED that a leading consumer television show has initiated an investigation into the presence of medical device company representatives in the operating theatre during surgical procedures.

We would like to outline for you the rationale behind this practice within the borders of South Africa, and the steps that SAMED has taken in this regard in the recent past.

One of the greatest risks during a surgery remains the anaesthetic time that the patient undergoes. As you know, there is a major shortage of skilled professional staff in the health care sector, particularly in the nursing arena. This means that often procedures performed without the availability of such personnel can take longer than is necessary, and this clearly puts patients at risk due to the longer anaesthetic time.

This statement attempts to answer the question as to why such procedures take longer and may put the patient at risk, and the role that a representative from a medical device company can play in the hospital environment / operating theatre, that will be of benefit to the patient.

In the surgical field there are many specialities, however only a few theatre nurses have the benefit of being able to specialise themselves. Even among this group of speciality-trained theatre nurses, many will at some time be asked to work with a surgeon in a discipline in which they have not been fully trained. (We must at this point specify that the training and expertise is with regard to the very specialised and specific instrument sets that our member companies send out on loan for procedures to the hospitals.) A nurse who may, for example, work primarily with surgeons who are Gynaecologists may be asked to work with a surgeon with another speciality.

While there is no doubt that for a standard procedure the said nurse will have no problem making that adaptation, a problem can often arise when the surgeon requires a specific solution to a clinical problem that will involve the introduction of a loan instrumentation system or even a product that is not held as standard within the hospital.

It is at this point that medical device companies provide the service of a representative / professional together with the instrumentation system/s which are ordered for the surgery.

It is the responsibility of the company representative to ensure that the instrumentation and intellectual capital of those systems are portrayed both efficiently and timeously to the sister and the surgeon in the operating theatre. Essentially, the representative's responsibility is to facilitate the effective and efficient flow of complex instrumentation to the scrub sister who in turn hands the instruments to the surgeon.

Instrument sets can be very complicated and often require assembly during the procedure/s. If the theatre staff are not fully conversant with the sets, which is often not possible simply due to the sheer number of different systems available, and if there was no company representative present, it could potentially lead to complications during the procedure and almost certainly prolong the anaesthetic time to which the patient would be subjected.

For decades medical device company representatives in South Africa (and elsewhere) have been in and out of operating theatres advising on and assembling loan systems for theatre staff. In the recent past SAMED undertook to identify acceptable standards for such personnel. To do this, we partnered with a professional body, namely the SAOA (South African Orthopaedic Association), in order to facilitate a course for representatives who find themselves within the clinical environment.

Amongst the criteria that the representatives will undertake to address are:

1. Compliance with healthcare institution Rules / Guidelines
2. The Constitutional Rights of Patients
3. Legal review
4. Ethics
5. Blood Borne Pathogens
6. Data Privacy
7. Control policy
8. Aseptic Techniques
9. That the Healthcare Professional (HCP, Doctor / Surgeon) has received informed consent from the patient for the representative to be present during the procedure.

10. That the relevant HCP has requested that the representative be present.
11. Management of the relevant surgical device is an exclusive interaction between the company representative and the person assisting the HCP / Surgeon.

SAMED has additionally had meetings with the three major private hospital groups to ensure support for this initiative as well as compliance with and enforcement of the protocols. Furthermore we have requested a meeting with government to discuss this issue.

The intention is that on completion of the course, which is to be registered at the requisite SETA, a candidate will be issued with an ID card which will be a prerequisite to entering the clinical environment. This card will have a validity of 3 years, after which a refresher course will be mandatory. In addition medical device companies will be required to ensure that their personnel regularly complete internal product training to ensure adequate competency of their representatives.

Should you have any further questions please contact me.

Regards

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