

**ARE COMPANY REPRESENTATIVES
ADEQUATELY TRAINED TO BE IN
OUR THEATRES, ICU'S AND CSSD'S?**

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THE ANSWER TO THE QUESTION !

- ▶ In the past in many cases the answer was **NO!**
- ▶ Industry recognised the need to rectify a potentially disastrous situation

**The concept of
CRICE was born!**



LEGAL RAMIFICATIONS

- ▶ *Zappola v Leibinger* 2006 WL 1174448 (Ohio App, 8 Dist. 2006) representative incorrectly informed the physician
- ▶ *Adkins v Cytec Corp* 2008 WL 2680474 (W.D. Va. 2008) *the sales representative's actions as those of a 'de facto' physician's assistant during a surgical procedure*
- ▶ *Hurley v The Heart Physicians, P.C.*, 898 A.2d 777 (Conn.2006) *the learned intermediary doctrine was not an available defence for the company*
- ▶ *Van Vuuren and Another NNO v Kruger* 1993 (4) SA 842 (SAA) The plaintiff alleged that his right to privacy was violated when a medical practitioner disclosed his HIV-positive status to a third party. Claim of R50,000 Appeal court increased to R250,000.



INDUSTRY'S RESPONSIBILITY

- ▶ To protect patients, itself and hospitals
- ▶ To assess requirements
- ▶ Bring together industry players to discuss potential solutions
- ▶ Bring together hospital groups to discuss potential solutions
- ▶ Implement and effect strategy around the solutions

3 MODULES

▶ Module 1

- ▶ Ethics
- ▶ Professionalism

▶ Module 2

- ▶ Infection Control
- ▶ Additional Precautions
- ▶ ICU Procedure (Hand washing)
- ▶ Universal Precautions
- ▶ Operational Exposure

▶ Module 3

- ▶ Medical and Legal Aspects
- ▶ Out of Scope Behaviour
- ▶ Breach of Confidentiality

NOW MODULE 4

- ▶ Module 4 CSSD (Will be implemented by Q4 2019)
 - ▶ Covers Loan and Consignment sets
 - ▶ In line with SANS 1541:2014
- ▶ Pre Theatre
 - ▶ Written Policy
 - ▶ Service Level Agreements
 - ▶ Notification to supplier and Preparation
 - ▶ Receipt and Inspection
 - ▶ Clean, Inspection, Disinfection and Sterilisation
 - ▶ Stage and Transport

NOW MODULE 4 (CONT)

- ▶ In Theatre
 - ▶ Inspection
 - ▶ Use as per IFU
 - ▶ Intra Operative Cleaning
 - ▶ Transport

NOW MODULE 4 (CONT)

▶ Post Theatre

- ▶ Clean, Inspect, Disinfect and Sterilise
- ▶ Issuance of Decontamination Certificate
- ▶ Inventory Transport and Storage

BASIC PRINCIPLES

- ▶ Patient Safety is paramount
- ▶ CSSD staff are trained and considered experts on the various types of sterilisation
- ▶ CR NEVER to perform any decontamination activities
- ▶ 10 Simple steps to ensure proper management of loan sets from arrival to departure
- ▶ This entire process was structured on evidence based practices
- ▶ You need to do your part to ensure patient safety

HOSPITAL SOP



- ▶ Are these enforced?
- ▶ Do your CSSD staff know what the SOP's are with regard to external people?
- ▶ What does your SOP say in the event of something going wrong?
- ▶ Ultimately who is responsible?
- ▶ Do you check that a company representative has either a blue or green CRICE card?

thank you!