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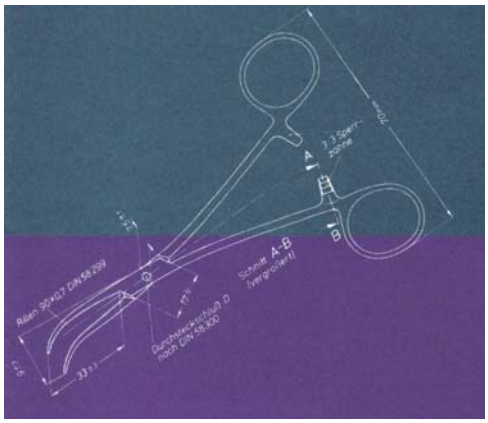
Responsibilities of the parties involved



Congress VDSMH 22.11.07: Design surgical instruments, safety of the patient first

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Which are the liable parties with regard to the safety of surgical instruments, according to the Dutch Civil Code?

1. The doctor using the surgical instrument
2. The hospital where the patient is treated with the surgical instrument
3. The manufacturer of the surgical instrument

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1. Responsibilities of the doctor using the surgical instrument

A large extent of carefulness can be expected of the doctor treating the patient towards the adequacy of the instruments used.

The treating doctor can be held responsible if he or she uses an instrument not meeting the demands that can be made of the instruments giving the circumstances (article 6:173 and 181 Civil Code).

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2. Responsibilities of the hospital where the patient is treated with the surgical instrument

A large extent of carefulness can be expected of the hospital too, towards the adequacy of the equipment used.

The hospital has a central liability for injuries sustained (blameworthy) during the performance of the medical agreement of treatment (article 6:462 and 6:77 Civil Code).

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This responsibility does not only apply to the choice of the surgical instrument (suitability for the purpose of application), but does apply also to the way the surgical instruments are cleaned, disinfected, sterilized and maintained within the hospital.

The cleaning of the surgical instruments requires (amongst others) the 'Decree sterilized medical tools in hospitals', as well as directives drawn up by the Study group Prevention of Infection and the directives drawn up by the NEN. Together these regulations and directives make up the professional standard.

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Three of the main cornerstones of the 'Decree of sterilized medical tools hospitals' are:

1. The duty to keep a file containing all of the relevant data of the methods of sterilization applied (article 3);
2. The duty to draw up a protocol of the sterilization of every party, with reference to the control of the sterilization process (article 7);
3. The duty to a regular supervision of the efficiently functioning of the medical equipment applied, as well as the registration of this supervision (article 10).

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In case the DSMH or the employees of the CSA act contrary to these regulations and/or directives and as a result a patient suffers damages (personal injury), the hospital, as the employer of the DSMH and the employees of the CSA, can be held liable.

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Under which circumstances is the doctor/hospital not responsible?

In case the instruments are failing because the manufacturer put the product on the market with a deficiency not recognisable by experts. In that case, liability of the manufacturer in the first place is evident.

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Reporting a problem/deficiency

When the doctor/hospital finds a deficiency/problem with a surgical instrument the doctor/hospital should report the problem to the manufacturer. Manufacturers have a legal obligation to investigate the problems that occur with their products. If there is a structural problem or a serious adverse event the manufacturer is also obligated to inform the Healthcare Inspection.

The doctor/hospital can also report the deficiency directly to the Healthcare Inspection, if he or she gets insufficient response from the manufacturer.

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4. Responsibilities of the manufacturer of the surgical instrument

If, during the medical treatment, damage is caused because of the use of a deficient product, the manufacturer is responsible.

A product is deficient when it does not offer the safety which may be expected of the product, all circumstances considered (article 6:185 and 186 Civil Code).

For a manufacturer of a medical device, the 'Decree Medical Instruments' is relevant.

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The main cornerstones of the 'Decree Medical Instruments' are:

- Medical instruments have to meet essential requirements: (article 6):
  - general requirements
  - design- and construction requirements
- Whether or not an instrument meets these requirements, will be judged on the basis of procedures which judge the conformity (depending on the grade of risk) (article 9).
- CE-marking is necessary to enable the manufacturer to put the instrument on the market (article 7).

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Under which circumstances is the manufacturer not responsible?

a) In case the deficiency has occurred at a later stage.

b) In case the product was in accordance to the state of art, at the moment it was introduced to the market.

c) In case the doctor and/or the hospital themselves are the manufacturer of the deficient product.

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Judgement Court of Arnhem, September 7, 2004

Case:
A hospital was held responsible by a patient for the consequences of the execution of a knee surgery (2000) performed with an arthroscope that was not sterilized but had only been disinfected, and therefore was not suitable for the execution. After the surgery of the knee, an infection occurred in the joint of the knee.

It was beyond doubt that the arthroscope had been disinfected with Cidex (chemical liquid) instead of sterilisation by steam.

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I an intermediate judgement the judge ruled that the hospital had to prove that:

1. The disinfection of an arthroscope with Cidex instead of (sterilisation with) steam on January 4, 2000, was at the time, in accordance with the law on medical instruments, with the protocols valid in the hospital, with an advice of the Inspector of Healthcare concerning sterilization (of arthroscopes) and with medical specialist literature;
2. If and in which degree on January 4, 2000, other hospitals in The Netherlands did switch regarding the purification of arthroscopes from disinfection with Cidex to another method of sterilization, mainly steam.

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The hospital did not succeed to meet the requirement of the burden of proof, because:

1. According to the document 'Purification, disinfection and sterilization of fiberoptical scopes and fixed (starre) scopes', endoscopes used for diagnostically or therapeutically purposes in primary sterile organs or tissues have to be sterile before use;
2. The instructions of Cidex warn that a critical medical instrument that normally penetrates the skin or mucous membranes and the circulatory system during its use, or that is used in body tissue that is generally sterile, produces a high risk when not sterile.

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de Gelderlander

30-08-2007

Hiv-alarm in Brabants ziekenhuis

OSS/VEGHEL - Vijfhonderd patiënten van ziekenhuis Bernhoven in Oss en Veghel zijn mogelijk besmet met het hiv (het virus dat aids veroorzaakt), hepatitis B of hepatitis C.

Door een technische fout in vier nieuwe, zogeheten scopendesinfectoren (wasmachines), zijn slangen die gebruikt worden voor kijkonderzoek in maag, longen of darmen waarschijnlijk niet goed gereinigd. Het ziekenhuis benadrukt dat de fout in de machines zit en dat hem ziekenhuis geen blaam treft. Bernhoven heeft leverancier Sanamij uit Rotterdam verantwoordelijk gesteld. Van dat bedrijf was woensdagvond niemand bereikbaar voor commentaar.

Conclusion

The doctor, the hospital and the manufacturer all have their own responsibility, towards the patient, with regard to the safety of surgical instruments, and they can all be called to account on this matter according to the Civil Code.

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''Better safe, than sorry!''