THESIS TITLE	LEGAL MEASURES OF CONSUMER PROTECTION RIGHT : A CASE STUDY OF MEDICAL DEVICES IN TYPE OF IMPLANTED SILICONE BREAST PROSTHESIS
KEYWORDS	IMPLANTED SILICONE BREAST PROSTHESIS
STUDENT	APIRAK KONGKAPET
THESIS ADVISOR	DR. NISIT INTAMANO
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ABSTRACT

The objective of this thesis is to study background, concept, theory, meaning, criteria and measure of civil law in relation to consumer protection in the area of medical device in type of implanting silicone artificial breast; and to find the guideline of revision in existing laws for consumer safety protection in appropriate and effective use of medical device in type of implanted silicone breast prosthesis for international conformity according to the finding of the study, even though there have been Law of Consumer Protection from Use of Implanting Silicone Artificial Breast as enacted in Civil and Commercial Code in the way of violation, Medical Device Act B.E. 2551 (2008), Consumer Protection Act B.E. 2522 (1979) and Revision, Liability on Dangerous Goods Caused Damage Act B.E. 2551 (2008), Medical Professional Act B.E. 2525 (1982) and Notification of Ministry of Public Health (Issue No. 23) B.E. 2540 (1997) on implanted silicone breast prosthesis, in Thailand. However, various problems have still been occurred. It was to say that pursuant to the Notification of the Ministry of Public Health (Issue No. 23) B.E. 2540 (1997) on Implanting Silicone Artificial Breast, it prescribes that implanted silicone breast prosthesis is the medical device in type of which the manufacturer or importer shall notify just detail to the Food and Drug Administration without requirement of property inspection or pass of standard certification for this type of medical device at all. In addition, the sale of medical device in type of implanted silicone breast prosthesis has not yet been controlled. The unclear label problem has resulted in ineffective and inadequate control and supervision on

quality and standard. Moreover, the problem of low standard of physician as the user of this type of medical device has caused the failure to treat consumers without delay upon damage occurrence against the consumers from use of implanted silicone breast prosthesis. For the aforesaid reasons, laws should be revised under revision on the Notification of the Ministry of Public Health on Implanted Silicone Breast Prosthesis prescribing that implanted silicone breast prosthesis is the medical device in type of which permission is required; addition of the clarity of label regulation and determination of the qualification of the physician as the user of this type of medical device to be the specific physician and revision on Medical Device Act B.E. 2551 (2008) by determining selling control measure on prohibition of direct sale and permission to sell particularly in clinic or beautification clinic certified for medical professional engagement in surgery, and determining the measure of treatment and damage compensation from use of implanted silicone breast prosthesis. The measure of damage compensation shall be applied without requirement for proof of offence, etc.