

Iyakuan released No.43

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To: Chairman of Japan Medical Devices Association

From: Pharmaceutical and Medical Safety Bureau Chief of MHLW

**Instruction to revise the Instruction For Use
regarding to the Pharmaceutical Affairs Law, 2 of Article No63 - No.1**

In December 2000, a paper has been published regarding of nickel or molybdenum elution from coronary artery stents made of stainless steel (henceforth stent) might increase restenosis incidents to the patients with metal allergy.

At this moment, it is unclear coronary artery stents made of stainless steel cause allergic reaction against nickel or molybdenum. However, according to the investigation targeted stents implanted patients described in this paper, the restenosis incident rate are greater among the stent patients with metal allergy comparing to the patients without the allergy. Thus, it will be appropriate to check whether a patient is predisposed to metal allergy before stent implant or not, and if so, the appropriateness of stent implantation should be reconsidered.

Moreover, it is adequate to provide this information about the risk of restenosis incidents increase caused by metal allergy while using stents to medical facilities. Thus, you should inform your membership companies to request that the description on the Instruction For Use should be revised based on the Pharmaceutical Affairs Law, 2 of Article No63 - No.1.

ACCOUNT

1. The statement below should be added as required description based on the Pharmaceutical Affairs Law, 2 of Article No63 - No.1:

Indication of this product is to implant in a blood vessel. While its usage metallic content might be eluted and there is a possibility of causing allergy to metal.

There is a report suggesting a possibility of decrease on stents efficiency in this case. Thus doctors should have history talking, and if a patient predisposed to metal allergy, the appropriateness of stent treatment should be reconsidered.

2. "*Lancet 2000; 12:1895-1897,*" the paper mentioned above, should be provided as reference document.