

**NIPPON KINZOKU's Original Steel Grade "NK-304LCO"  
Start of Sales of Stainless Steel Materials for  
Injection Needles to Europe and China  
Compliant with the European Medical Device  
Regulations Cobalt Composition Regulations**

NIPPON KINZOKU CO., LTD. commercialized "NK-304LCO" stainless steel for injection needles in November 2020, which is compliant with the Cobalt composition regulation of the European Medical Devices Regulation (MDR), which came into effect in May 2021 and will be fully transitioned on 31 December 2028.

We would like to announce that we are currently making progress in expanding sales to overseas markets.



Insulin needle (typical needle size: 32G)

The MDR is a regulation for marketing medical devices in Europe and is a stricter approval system than the existing Medical Device Directive (MDD). The MDR stipulates the Regulation on Classification, Labeling and Packaging of substances and mixtures (CLP), which targets the cobalt (Co) component contained in stainless steel as a carcinogen. It is less than 0.1%.

Conventional NK-304NKM stainless steel for injection needles was difficult to adapt to this regulated quantity, but in response to requests from domestic and overseas medical device manufacturers, we have succeeded in alloy design (composition adjustment) as a result of discussions with raw material manufacturers. We were able to successfully supply the material.

Currently, we have started selling the amount equivalent to approximately 3% of the cobalt-regulated materials for customers using our stainless steel material for injection needles. The complete transition to MDR has been postponed from the original May 2024 to December 2028, volumes are currently increasing slightly due to the regulatory approach of individual medical manufacturers, but enquiries from the European and Chinese markets are increasing and sample shipments have already begun.

The price of NK-304LCO, which complies with Co regulations, is higher than conventional NK-304NKM because of the cost of component adjustment at the raw material manufacturer and the need for steel producing extras. However, we are able to handle small lots in the same way as NK-304NKM, thereby reducing the burden on the customer as much as possible.

The NK-304NKM has been selected as the material of choice for "thin diameter" types of needles for insulin such as "painless needles" and cosmetic applications, and is currently being used all over the world. The sales share (\*1) of our materials for injection needle applications is approximately 49% in Japan and 59% overseas (\*2), with an average share of approximately 55%, and our quality superiority is widely recognized in the injection needle market. In addition to maintaining a high market share, sales to the Chinese and Indian markets are expected to expand in the future due to the increasing number of diabetes patients worldwide.

We humbly accept that the quality of our products, which is born from our unique technology, and our flexible response to the needs of changing times, will lead to a proven track record and trust. We are determined to actively take up the challenge of further expanding our sales in domestic and overseas markets.

\*1 : 32 domestic and international companies, surveyed by us in October 2023.

\*2 : Overseas principal countries are South-East Asia, South Korea, China, India and the EU

## ● Features of the NK-304LCO

### 1. Processability without rupture even at high drawing rate

Injection needles are manufactured by welding the edge of the material and then stretching the raw tube into a thin tube. For insulin, for example, a raw tube with a diameter of 4.0 mm and a wall thickness of 0.2 mm is drawn, then heat-treated and drawn many times in turn, until it is drawn to an outer diameter of 0.18 mm and a wall thickness of 0.05 mm.

"Processability without rupture even when at high drawing rate" and "Stability of the welded part of the bare tube that does not fracture even when thinly drawn" are particularly important in this process.

Our stainless steel for injection needles, "NK-304LCO", is within the SUS304 composition of the Japanese Industrial Standards (JIS) and the American Iron and Steel Institute (AISI) standards, suppresses work hardening and increases processing performance.

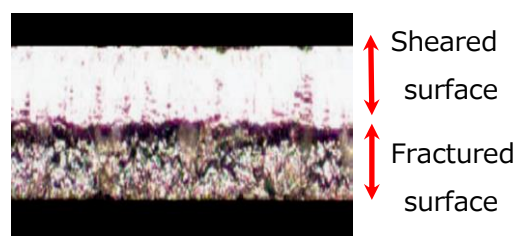
### 2. Stability of the welded part of the bare tube and cutting surface of the material, which will not rupture even when thinly drawn.

The ratio between the fractured and sheared surfaces is agreed to facilitate welding by medical device manufacturers.

The same end-face properties are supplied for the entire coil length (0.2 mm: approx. 4,000 M).  
(※Reference: Image on the right)

【Cutting surface management】

Ratio of sheared surface 50%



"NK-304NKM", which is the base of "NK-304LCO", is a steel grade developed on the premise of versatility in forming by medical device manufacturers.

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