

# Medical Device Producer

## Objective

Ensure that a prosthesis used in lumbar spine surgery is not exposed to temperatures exceeding 60°C from the time it leaves the manufacturing facility until it is used in the operating room.

## Strategy

The manufacturer chose ATI high temperature ascending (HTA) labels to prevent high temperature damage to its prosthesis product during transit and storage. A white viewing window on the HTA labels will permanently turn red if the temperature exceeds 60°C.

## Implementation

The HTA labels are placed on each product carton at the manufacturing facility. At every transfer point – from the warehouse or distribution center to the medical facility to the operating room – personnel easily verify that the high temperature limit has not been exceeded.

## Results

Surgeons who use the prosthesis are assured that the viability of the product has not been compromised by excessive temperatures. The labels also highlight the quality assurance commitment of the manufacturer, further enhancing consumer confidence.

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