



Instruction for Use – Device-  
Specific Instrument Reprocessing  
Instructions

Document: 101-6003

Rev: B

Page 1 of 7

Date: 08/28/20

**NanoOrtho, LLC.**

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# nanoknee®

Unicompartmental Knee System

# Instructions for: Device-Specific Instrument Reprocessing, Inspection, and Maintenance

The information contained in this package insert was current on the date this brochure was printed. However, the package insert may have been revised after that date. To obtain a current package insert please contact NanoOrtho, LLC at the contact information provided herein.

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## Appendix 1: Disassembly Instructions for cleaning & Visual Inspection

Instructions for device-specific instruments and instrument assemblies that require disassembly

Part #	Instrument Name	Surgical System	Instructions
101-5000 & 101-5001	Tibial EM Alignment Guide & Tibial EM Alignment Guide Top Shaft	 <p>Tibial EM Alignment Guide 101-5000</p>  <p>Tibial EM Alignment Guide Top Shaft 101-5001</p>	<ol style="list-style-type: none"> <li>Loosen the thumb screw on the top of the Tibial EM Alignment Guide by partially unthreading the thumb screw counter-clockwise;</li> <li>Remove the Tibial EM Alignment Guide Top Shaft by sliding it out of the Tibial EM Alignment Guide</li> </ol>
101-5001 & 101-5002	Tibial EM Alignment Guide Top Shaft & Tibial Cutting Guide Adapter Mount	 <p>Tibial Cutting Guide Adapter Mount 101-5002</p>  <p>Tibial EM Alignment Guide Top Shaft 101-5001</p>	Firmly slide the Tibial Cutting Guide Adapter Mount in the direction away from the slot in which it engages with the Tibial EM Alignment Guide Top Shaft

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<p>101-5002 &amp; 101-5003</p>	<p>Tibial Cutting Guide Adapter Mount &amp; Tibial Cutting Guide</p>	 <p>Tibial Cutting Guide Adapter Mount 101-5002</p> <p>Tibial Cutting Guide 101-5003</p>	<p>Separate the Tibial Cutting Guide from the Tibial Cutting Guide Adapter Mount by gently pulling the Tibial Cutting Guide away from the mating surfaces between the two instruments</p>
<p>101-5014 &amp; 101-5015</p>	<p>Extramedullary Alignment Rod &amp; Drop Rod Assembly</p>	 <p>Extramedullary Alignment Rod 101-5014</p> <p>Drop Rod Assembly 101-5015</p>	<ol style="list-style-type: none"> <li>1. Unthread the male alignment rod from the female alignment rod by turning counter-clockwise;</li> <li>2. Remove the alignment rod pieces from the Drop Rod Assembly</li> </ol>
<p>101-5021 &amp; 101-5022</p>	<p>Tibial Impactor Handle &amp; Tibial Impactor Head</p>	 <p>Tibial Impactor Head 101-5022</p> <p>Tibial Impactor Handle 101-5021</p>	<ol style="list-style-type: none"> <li>1. Depress the thumb lever on the Tibial Impactor Handle;</li> <li>2. While the thumb lever is depressed, slide the Tibial Impactor Head away from the Tibial Impactor Handle along the dovetail connection</li> </ol>
<p>101-5025 &amp; 101-5026</p>	<p>Alternative Impactor Handle and Alternative Impactor Head</p>	 <p>Alternative Impactor Handle 101-5025</p> <p>Alternative Impactor Head 101-5026</p>	<p>Unthread the Alternative Impactor Head from the Alternative Impactor Handle in a counter- clockwise direction</p>

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Rev: B

Page 4 of 7

Date: 08/28/20

<p>101-5021 &amp; 101-5024</p>	<p>Tibial Impactor Handle &amp; Tibial Impactor Peg Pre-Punch Head</p>	<p>Tibial Impactor Peg Pre-Punch Head 101-5024</p> <p>Tibial Impactor Handle 101-5021</p>	<ol style="list-style-type: none"> <li>1. Depress the thumb lever on the Tibial Impactor Handle;</li> <li>2. While the thumb lever is depressed, slide the Tibial Impactor Peg Pre-Punch Head away from the Tibial Impactor Handle along the dovetail connection</li> </ol>
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			Rev: B

## Appendix 2: Reassembly Instructions

Reassembly of device-specific instruments is to be performed by the surgeon. For additional information on surgeon reassembly, please review Surgical Technique documents (101-SRG01 and 101-SRG02)

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## Appendix 3: Visual Inspection Criteria for Wear and Tear

1. Carefully inspect each device to ensure that all visible contamination has been removed. If contamination is noted repeat the cleaning/disinfection process.
2. Visually inspect for completeness, damage and/or excessive wear.
  - a. Note: If damage or wear is noted that may compromise the function of the instrument, contact your NanoOrtho Representative for a replacement.
3. Check the action of moving parts (e.g. hinges, connectors, sliding parts, etc.) to ensure smooth operation throughout the intended range of motion.
4. If necessary, hinged, rotating, or articulating instruments can be lubricated with an instrument product (e.g. Instrument Milk or equivalent lubricant) specifically designed for compatibility with steam sterilization.
  - a. Note: These lubrication instructions are not applicable to air-powered or electrical instruments. These devices have different requirements and should be lubricated according to the manufacturer's instructions.
5. Check instruments with long slender features (particularly rotating instruments) for distortion.
6. Where instruments form part of a larger assembly, check that the devices assemble readily with mating components.

### Visual Check for multiple use Drill Bits (i.e. 101-5019 Femoral Peg Drill)



*101-5019 (Femoral Peg Drill)*

#### Potential Failure Modes:

- Defective coupling end (eroded)
- Blunt and dull cutting flutes
- Tips, helix coil, bent

Preventive Maintenance: Regular functional check and visual inspection. In case of failure, the instrument must be replaced and not be used.

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**Visual Check for instruments with threaded connections**

**Potential Failure Modes**

- Damaged and/or squeezed threads
- Malfunction due to wear
- Corrosion or contamination

Preventive Maintenance: Regular functional check and visual inspection. In case of failure, the instrument must be replaced and not be used.

**Information:**

Comments regarding the use of this device can be directed to:

Attn: Customer Service, NanoOrtho LLC, 860 Oak Park Blvd., Suite 301. Arroyo Grande, CA 93420, USA  
 TEL: +1 (805) 202-3321  
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 EMAIL: [service@nanoortho.com](mailto:service@nanoortho.com)

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