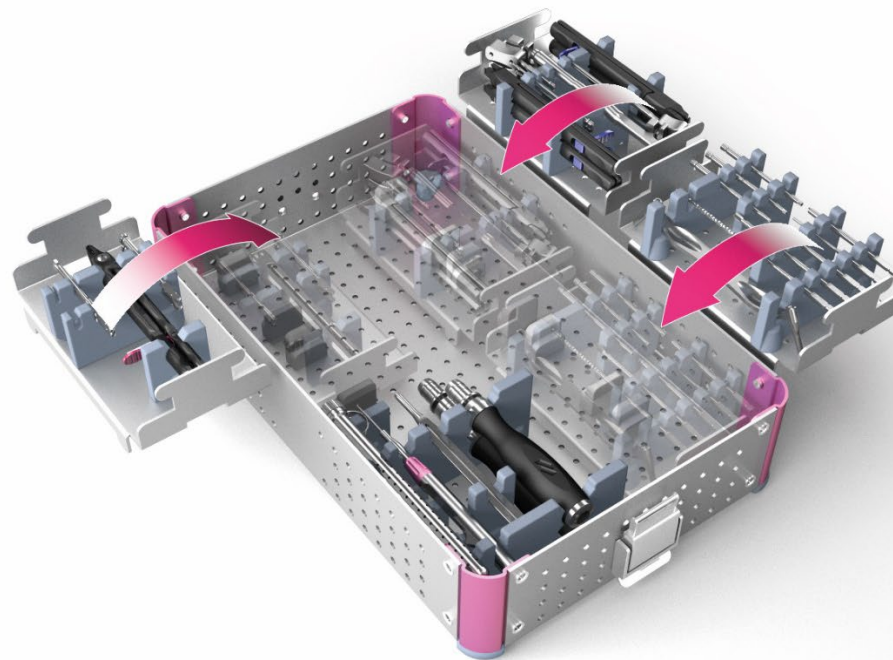




## Instruction on the Inspection of Reusable Medical Devices



## 1. INTRODUCTION

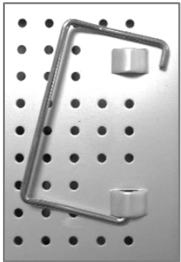
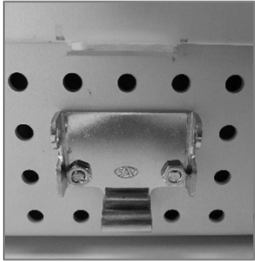

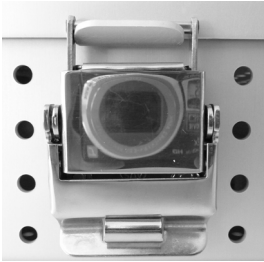


The purpose of this document is to describe the inspections the user needs to perform to guarantee the proper functioning of reusable medical devices from NOVASTEP. Refer to the label and package leaflet to establish whether the instrument is reusable.




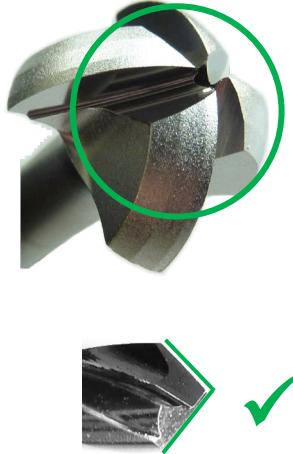
In general, these dysfunctions may be related to poor maintenance or inappropriate use of the device, which may continue until the end of its useful life.

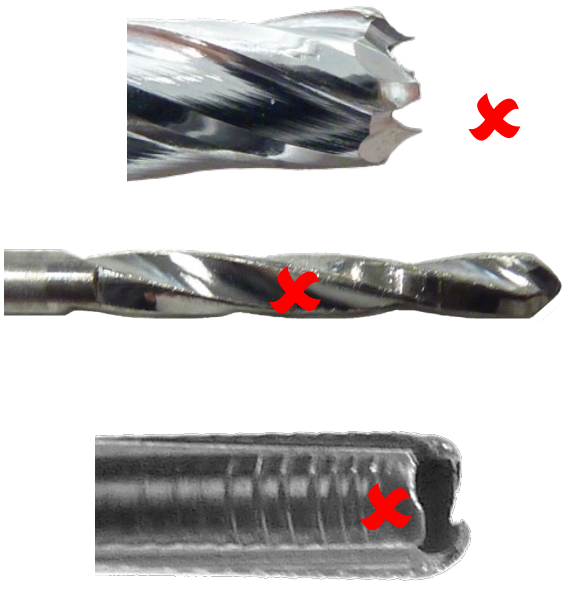
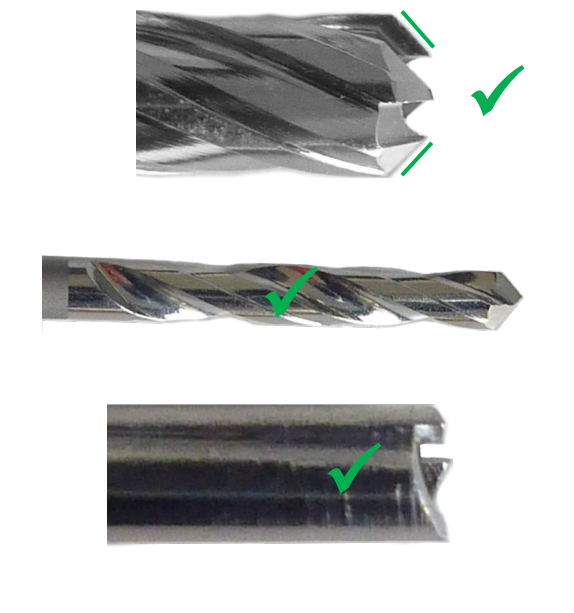
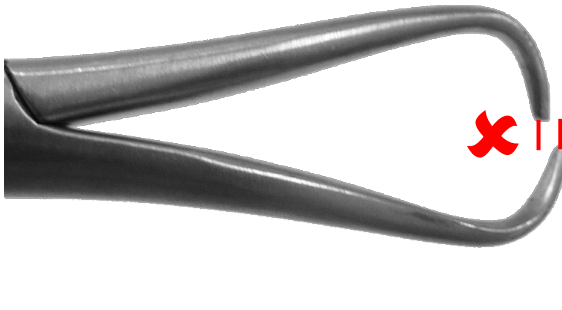

Because a high number of factors which are dependent on the user may impair the devices, NOVASTEP does not recommend a maximum number of uses. Rigorous inspection, associated with functional tests if applicable, will make it possible to check the performance of the reusable device and its proper operation throughout its entire useful life.

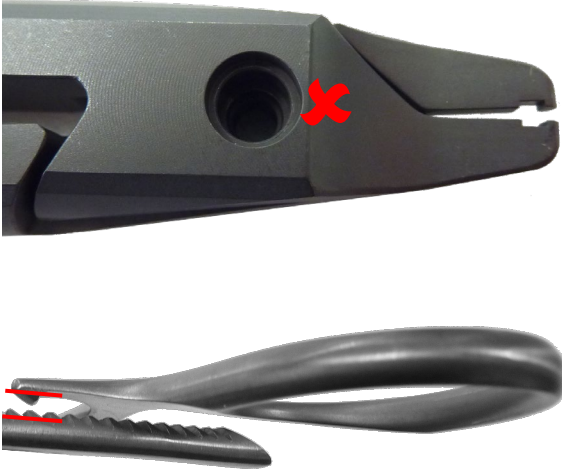
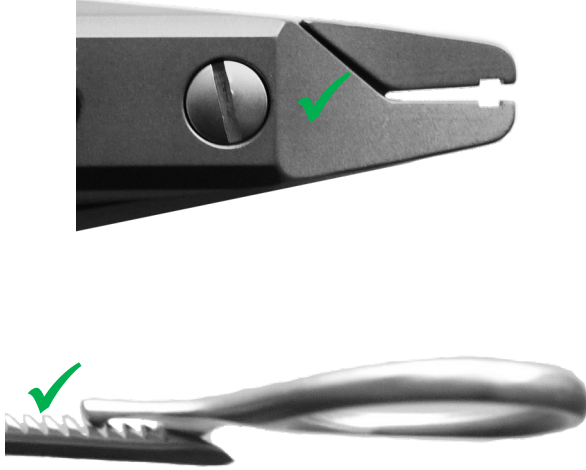


## 2. INSPECTION

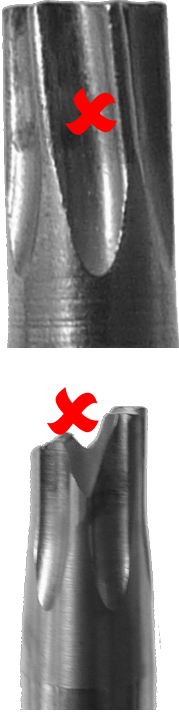
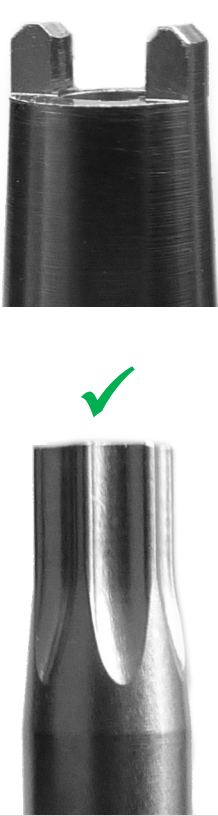


Take precautions when handling blunt and sharp instruments. If necessary, disassemble the device to perform the inspection and reassemble it according to the information provided in the Surgical Technique.

Criteria	Instructions for visual and functional inspection of the whole device.	Example of defect requiring replacement of the device	Example of the non-defective device
<b>Condition of sterilization trays</b>	Appearance of the boxes and marking Operation of fasteners and handles	<div style="text-align: center;">  <p>Disassembled handles</p>  <p>Damaged fastener</p> </div>	<div style="text-align: center;">   </div>
<b>Condition of identifiers and markings</b>	Readability of markings No corrosion		

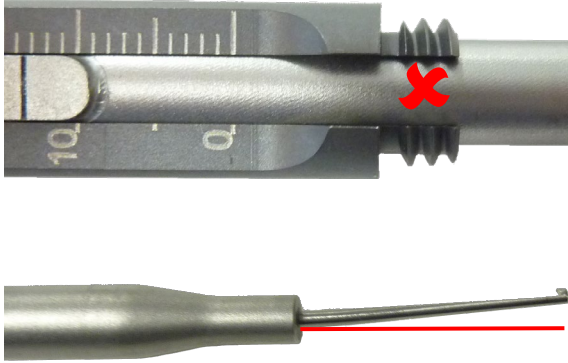
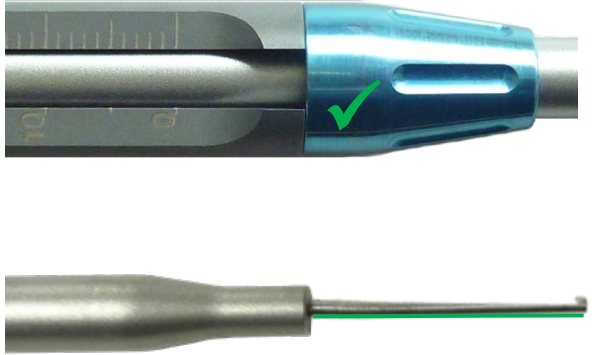
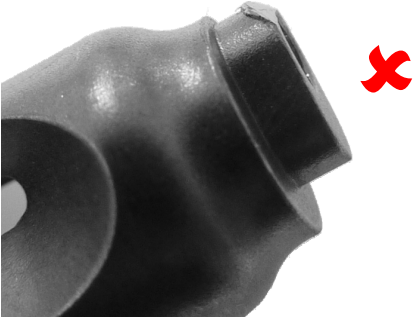
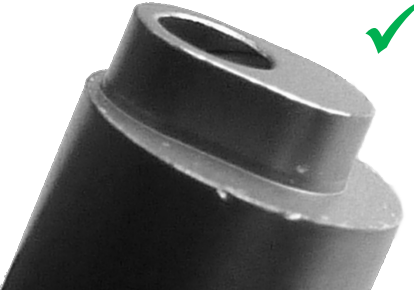
Criteria	Instructions for visual and functional inspection of the whole device.	Example of defect requiring replacement of the device	Example of the non-defective device
			
<p><b>Condition of cutting tools (drill, countersink, etc.)</b></p>	<p>The teeth and/or tips have not been knocked or deformed</p> <p>No blunt tip</p> <p>The cylindrical part is not deformed (concentricity)</p>		

Criteria	Instructions for visual and functional inspection of the whole device.	Example of defect requiring replacement of the device	Example of the non-defective device
			
<b>Condition of the forceps</b>	Closing and opening of the forceps Functioning of the springs Appearance of the active zones of the forceps (no burrs, deterioration or deformation) The screws are present and retain their holding ability Functioning of the racks		

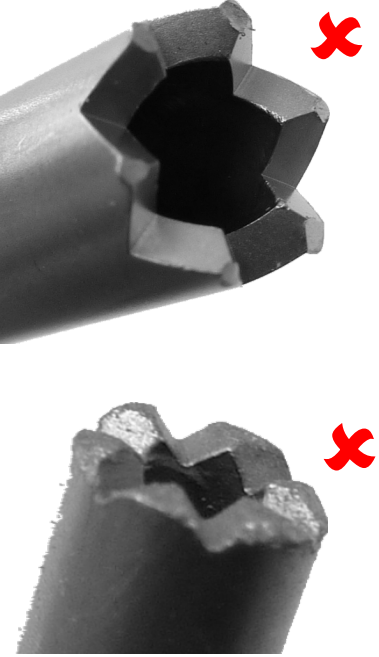
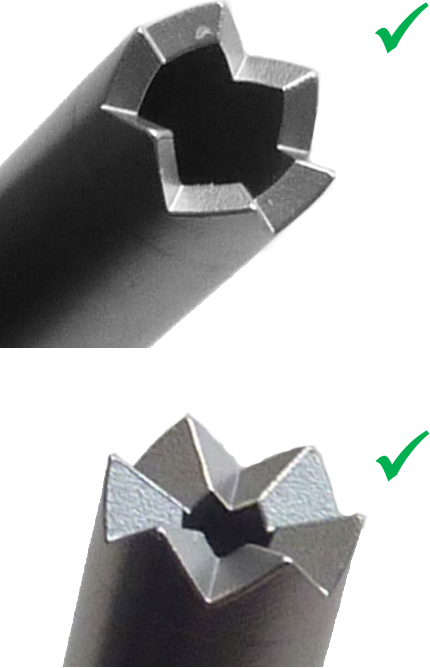
Criteria	Instructions for visual and functional inspection of the whole device.	Example of defect requiring replacement of the device	Example of the non-defective device
			
<b>Condition of the screwdrivers</b>	The screwdrivers have not been knocked, deformed or broken		



Criteria	Instructions for visual and functional inspection of the whole device.	Example of defect requiring replacement of the device	Example of the non-defective device
			
<b>Condition of the gauge</b>	Holding ability of the slide The screws are present Gauge reading Screwing of the gauge shank		

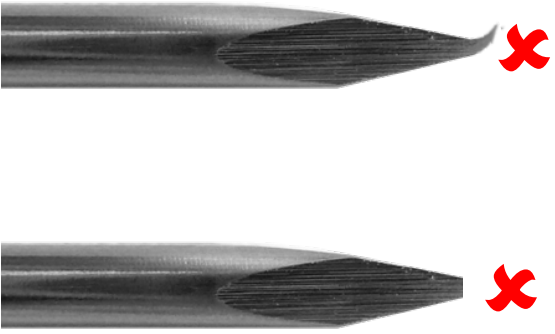
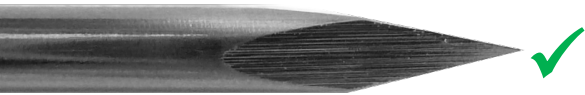


Criteria	Instructions for visual and functional inspection of the whole device.	Example of defect requiring replacement of the device	Example of the non-defective device
	Holding ability of the gauge bracket on the body		
<b>Condition of the cannulated or pierced instruments</b>	Use the appropriate pin to check that the cannula is not blocked  Check that the teeth have not been knocked or damaged		



Criteria	Instructions for visual and functional inspection of the whole device.	Example of defect requiring replacement of the device	Example of the non-defective device
			

Criteria	Instructions for visual and functional inspection of the whole device.	Example of defect requiring replacement of the device	Example of the non-defective device
<b>Condition of the threaded instruments</b>	Check the condition and functioning of the thread		

<p><b>Condition of the wires</b></p>	<p>The tip has not been knocked</p> <p>No deformation, bending or deterioration on the cylindrical part (darkening, grooves, high roughness, etc.)</p>		
<p><b>Condition of the handles and AO connections</b></p>	<p>Function of the click and lock mechanism using a connector</p>		



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**Ref. IIDM-Ed1-08-22-EN**