Functional Check

PG01, PG02 PG03

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Meaning of the symbols

	Consult instructions for use
	Caution, observe warnings

1. General Functional Check

This document contains general instructions for testing the functionality of Accuratus AG surgical instruments.

 Before using the instrument for the first time, please read the accompanying instructions for use and reprocessing carefully and thoroughly.

 The various instruments are designed for specific purposes. The tests must therefore be designed in such a way that instruments that no longer meet these purposes are reliably rejected.

 Frequent processing has only a negligible effect on the service life of the products. The end of the product's service life is normally determined by wear and damage caused by use. Therefore, after each reprocessing cycle, carefully check the product for functionality, damage, and signs of increased wear, corrosion, damaged surfaces, chipping, deformation, mobility, hairline cracks in the joint areas, etc.

 After each processing cycle, carefully check the product for functionality, damage, and signs of increased wear and corrosion.

 The inspection should be carried out for all instruments using a magnifying glass with a magnification of at least 3 diopters, preferably with a powerful light source.

 Products that show signs of increased wear or damage must not be reused under any circumstances and must be disposed of.

 Corroded instruments must be removed, as they can cause corrosion in intact instruments through the transfer of foreign rust.

 To prevent damage and subsequent corrosion (rust) caused by metal abrasion, under no circumstances should metal brushes or metal sponges be used to remove stains.

Limitations on reusability
The end of life of reusable medical devices is determined by wear and tear resulting from use and reprocessing.

Reusable medical devices are subject to wear and tear and mechanical stress even under normal use, but especially when excessive force is applied.

The end of life is determined by careful functional and visual inspection in each individual reprocessing cycle. For this reason, it is not possible to specify a general maximum number of cycles.

Medical devices that do not function properly, medical devices with markings that are illegible to humans or machines, missing or removed (worn) part numbers, damaged and excessively worn parts must not be used and must be repaired or disposed of.

The following evaluation criteria for the functional and visual inspection of surgical instruments are based on many years of experience. The following evaluation criteria are intended to assist in the detection of defects in the product or similar products.

1.1

PG01	04	Scissors
04.00.00 - 04.99.99		
		Visually inspect the instruments for damaged surfaces, chips, deformations, burrs—especially at the working end—and hairline cracks. If any such defects are identified, the products must be discarded. *Tool: Magnifying glass*
		Check the products for wear, especially on moving parts such as joints or locks and on the working ends. Check the products for loose parts, especially on joints, riveted or screwed connections. *Tool: Magnifying glass*
		Check the instrument for corrosion or surface changes that could promote the formation of corrosion (e.g., yellow-brown to dark brown localized discoloration, especially in hard-to-reach areas, such as grooves or joints). *Tool: Magnifying glass*
		Check the cutting surfaces carefully using a magnifying glass and sufficient lighting. Look for blunt blades, nicks, cracks, or chips. Blunt blades can be identified by the fact that they do not reflect light when illuminated directly. *Tool: Magnifying glass*

To check the cutting ability of instruments with two cutting edges (e.g., scissors), perform a cutting test on a Theraband. The material should be cut over 2/3 of the cutting length. Do not apply lateral pressure during cutting. The instrument must not snag during cutting.

The test material must be smooth, without any rough edges, the cutting length. Do not apply any lateral pressure during cutting. The instrument must not snag during cutting. The test material must be cut smoothly, without jamming, tearing, pulling, or pushing.

Tool: Magnifying glass, Theraband, fabric

Carefully check joints and moving metal sliding surfaces or instrument parts for excessive wear ("metal fatigue") and for loosening of connecting screws or rivets.

Tool: Magnifying glass

Joints must open and close evenly and without friction.

However, the joints of scissors must exhibit minimal resistance. To test this, perform a joint closure test on these instruments. Hold the instrument horizontally by both handles in a fully open position and then release the upper handle. The instrument should now close approximately 2/3 of the way, but not completely or close to the end.

Open position and then release the upper handle. The instrument should now close approximately 2/3 of the way, but not completely or "fall" into the closed position.

Oil joints and locks regularly with maintenance oil.

Tool: Magnifying glass

1.2

PG02	09	Clamps (for non-invasive use)
09.00.00 - 09.99.99		
PG02	13	Clamps (for non-invasive use)
13.00.00 - 13.99.99		

	Visually inspect the instruments for damaged surfaces, chipping, deformation, burrs—especially at the working end—and hairline cracks. If any such defects are identified, the products must be discarded. *Tool: Magnifying glass*
	Check the tools for wear, especially on moving parts such as joints or locks, as well as on the working ends. Check the products for loose parts, especially on joints, riveted or screwed connections. *Tool: Magnifying glass*
	Check the instrument for corrosion or surface changes that could promote the formation of corrosion (e.g., yellow-brown to dark brown localized discoloration, especially in hard-to-reach areas, such as grooves or joints). *Tool: Magnifying glass*
	Carefully check the working ends/mouthpieces of instruments for deformations,chips, burrs, scratches, or loosening of the joint. *Tool: Magnifying glass*

	To check that the jaw parts are symmetrical and correctly positioned, hold the instrument against a light source and close the jaw part. No light should penetrate the jaw part and both ends should lie flat against each other. *Tool: Magnifying glass*
	Toothed jaws should close cleanly and not jam or be difficult to open. Check the closure of toothed jaws by closing the instrument firmly and ensuring that the teeth close and reopen cleanly and symmetrically without snagging or jamming. *Tool: Magnifying glass*
	Ratchet locks should close securely and not open by themselves when counterpressure is applied. *Tool: Magnifying glass*
	Joints must open and close smoothly and without friction. However, the joints of clamps must exhibit minimal resistance. To test this, perform a closing test on the joint of these instruments. Hold the instrument horizontally by both handles in the fully open position and then release the upper handle. The instrument should now close approximately 2/3 of the way. To test the opening mechanism, hold the instrument horizontally by both handles in the fully open position and then release the upper handle. The instrument should now open approximately 2/3 of the way. To test the closing mechanism, hold the instrument horizontally by both handles in the fully open position and then release Hold the instrument horizontally by both handles in the fully open position and then release the upper handle. The instrument should now close approximately 2/3 of the way, but not completely or "fall" into the closed position. Oil joints and closures regularly with maintenance oil. *Tool: Care oil*

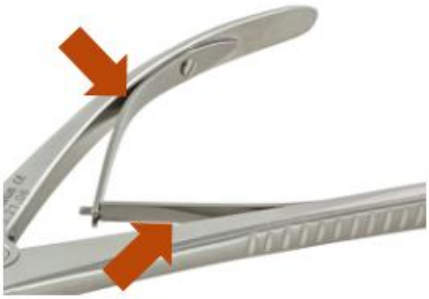
1.3

PG02	13	Spreader Forceps
13.00.00 - 13.99.99		
		Visually inspect the instruments for damaged surfaces, chipping, deformation, burrs—especially at the working end—and hairline cracks. If any such defects are identified, the products must be discarded. *Tool: Magnifying glass*
		Check the tools for wear, especially on moving parts such as joints or locks, as well as on the working ends. Check the products for loose parts, especially on joints, riveted or screwed connections. *Tool: Magnifying glass*
		Check the instrument for corrosion or surface changes that could promote the formation of corrosion (e.g., yellow-brown to dark brown localized discoloration, especially in hard-to-reach areas, such as grooves or joints). *Tool: Magnifying glass*
		Carefully check the working ends/mouthpieces of instruments for deformations, chipping, burrs, scratches, or loosening of the joint. *Tool: Magnifying glass*

	Carefully check joints and moving metal sliding surfaces or instrument parts for excessive wear ("metal fatigue") and for loosening of connecting screws or rivets. *Tool: Magnifying glass*

1.4

PG01	16	Gouge Forceps
16.00.00 - 16.99.99		
	Visually inspect the instruments for damaged surfaces, chipping, deformation, burrs—especially at the working end—and hairline cracks. If any such defects are identified, the products must be discarded. *Tool: Magnifying glass*	
	Check the tools for wear, especially on moving parts such as joints or locks, as well as on the working ends. Check the products for loose parts, especially on joints, riveted or screwed connections. *Tool: Magnifying glass*	
	Check the instrument for corrosion or surface changes that could promote the formation of corrosion (e.g., yellow-brown to dark brown localized discoloration, especially in hard-to-reach areas, such as grooves or joints). *Tool: Magnifying glass*	

	Carefully check the working ends/mouthpieces of instruments for deformations, chips, burrs, scratches, or loosening of the joint. *Tool: Magnifying glass*
	Carefully check joints and moving metal sliding surfaces or instrument parts for excessive wear ("metal fatigue") and for loosening of connecting screws or rivets. *Tool: Magnifying glass*

1.5

PG01	18	Bone Punches, Rongeurs
18.00.00 - 18.99.99		
		Visually inspect the instruments for damaged surfaces, chipping, deformation, burrs—especially at the working end—and hairline cracks. If any such defects are identified, the products must be discarded. *Tool: Magnifying glass*
		Check the instruments for wear, especially on moving parts such as joints and working ends. Check the products for loose parts, especially on joints, rivets, or screw connections. *Tool: Magnifying glass*

	Check the instrument for corrosion or surface changes that could promote the formation of corrosion (e.g., yellow-brown to dark brown localized discoloration, especially in hard-to-reach areas, such as grooves or joints). *Tool: Magnifying glass*
	Carefully check the working ends/mouthpieces of instruments for deformations, chipping, burrs, scratches, or loosening of the joint. *Tool: Magnifying glass*
	To check that the jaw parts are symmetrical and correctly positioned, hold the instrument against a light source and close the jaw part. No light should penetrate the jaw part and both ends should lie flat against each other. *Tool: Magnifying glass*
	Check blades and cutting surfaces carefully using a magnifying glass and sufficient lighting. Look for dull blades, nicks, cracks, or chips. *Tool: Magnifying glass*
	To check the cutting ability of instruments with two cutting edges, perform a cutting test on cardboard. The material should be cut over 2/3 of the cutting length. Do not apply lateral pressure during cutting. The instrument must not snag during cutting. The test material must be smooth, without any rough edges. blade length. Do not apply any lateral pressure during cutting. The instrument must not snag during cutting. The test material must be cut smoothly, without jamming, tearing, pulling, or pushing. *Materials: Paper / Cardboard*

	Regularly oil joints and fastenings with maintenance oil. *Tool: Care oil*

1.6

PG03	22	Wound retractors
22.00.00 - 22.99.99		
		Visually inspect the instruments for damaged surfaces, chipping, deformation, burrs—especially at the working end—and hairline cracks. If any such defects are identified, the products must be discarded. *Tool: Magnifying glass*
		Check the instrument for corrosion or surface changes that could promote the formation of corrosion (e.g., yellow-brown to dark brown localized discoloration, especially in hard-to-reach areas). *Tool: Magnifying glass*

	Carefully check the working ends/mouthpieces of instruments for deformations, chips, burrs, or scratches. *Tool: Magnifying glass*

1.7

PG03	24	Wound hook, bone levers	
24.00.00 - 24.99.99			
			Visually inspect the instruments for damaged surfaces, chipping, deformation, burrs—especially at the working end—and hairline cracks. If any such defects are identified, the products must be discarded. *Tool: Magnifying glass*
			Check the instrument for corrosion or surface changes that could promote the formation of corrosion (e.g., yellow-brown to dark brown localized discoloration, especially in hard-to-reach areas). *Tool: Magnifying glass*
			Carefully check the working ends/mouthpieces of instruments for deformations, chips, burrs, or scratches. *Tool: Magnifying glass*

PG03	24	Lever Extension
24.51.100		
		Visually inspect the instruments for damaged surfaces, chipping, deformation, burrs—especially at the working end. If any such defects are identified, the products must be discarded. *Tool: Magnifying glass*
		The DUPLUS lever extension is designed for all Subtilis bone levers and wound hooks with a two-hole handle. Check the slip resistance by attaching the lever extension and pulling it backward in the direction of the arrow.

1.8

PG01	29	Raspatories
29.00.00 - 29.99.99		
		Visually inspect the instruments for damaged surfaces, chipping, deformation, burrs—especially at the working end—and hairline cracks. Also check the condition of the plastic handle. If any defects are identified, the products must be discarded.

	Tool: Magnifying glass
	Check the instrument for corrosion or surface changes that could promote the formation of corrosion (e.g., yellow-brown to dark brown localized discoloration, especially in hard-to-reach areas). *Tool: Magnifying glass*
	Check blades and cutting surfaces carefully using a magnifying glass and sufficient lighting. Look for dull blades, nicks, cracks, or chips. Dull blades can be recognized by the fact that they do not reflect light when illuminated directly. *Tool: Magnifying glass*
	To check the cutting ability of instruments, perform a cutting test on plastic film (max. 100 g/m²). The material should be cut over 2/3 of the blade and produce a smooth, homogeneous cut. *Tool: Magnifying glass*

1.9

PG01	**31**	**Curettes**
31.00.00 - 31.99.99		
		Visually inspect the instruments for damaged surfaces, chipping, deformation, burrs—especially at the working end—and hairline cracks. Also check the condition of the plastic handle. If any defects are identified, the products must be discarded. *Tool: Magnifying glass*

	Check the instrument for corrosion or surface changes that could promote the formation of corrosion (e.g., yellow-brown to dark brown localized discoloration, especially in hard-to-reach areas). *Tool: Magnifying glass*
	Check blades and cutting surfaces carefully using a magnifying glass and sufficient lighting. Look for dull blades, nicks, cracks, or chips. Dull blades can be recognized by the fact that they do not reflect light when illuminated directly. *Tool: Magnifying glass*

1.10

PG01	34	Hammers
34.00.00 - 34.99.99		
		Visually inspect the instruments for damaged surfaces, chipping, deformation, burrs—especially at the working end—and hairline cracks. Also check the condition of the plastic handle. If any defects are identified, the products must be discarded. *Tool: Magnifying glass*
		Check the instrument for corrosion or surface changes that could promote the formation of corrosion (e.g., yellow-brown to dark brown localized discoloration, especially in hard-to-reach areas). *Tool: Magnifying glass*

	Inspect the connection for signs of material fatigue, particularly for cracks or discoloration. *Tool: Magnifying glass*

1.11

PG01	35	Chisels
35.00.00 - 35.99.99		
	Visually inspect the instruments for damaged surfaces, chipping, deformation, burrs—especially at the working end—and hairline cracks. Also check the condition of the plastic handle. If any defects are identified, the products must be discarded. *Tool: Magnifying glass*
	Check the instrument for corrosion or surface changes that could promote the formation of corrosion (e.g., yellow-brown to dark brown localized discoloration, especially in hard-to-reach areas). *Tool: Magnifying glass*
	Check blades and cutting surfaces carefully using a magnifying glass and sufficient lighting. Look for dull blades, nicks, cracks, or chips. Dull blades can be recognized by the fact that they do not reflect light when illuminated directly. *Tool: Magnifying glass*

1.12

PG01	36	Luxation Lever
36.60.03		
		Visually inspect the instruments for damaged surfaces, chipping, deformation, burrs—especially at the working end—and hairline cracks. Also check the condition of the plastic handle. If any defects are identified, the products must be discarded. *Tool: Magnifying glass*
		Check the instrument for corrosion or surface changes that could promote the formation of corrosion (e.g., yellow-brown to dark brown localized discoloration, especially in hard-to-reach areas). *Tool: Magnifying glass*
		Check blades and cutting surfaces carefully using a magnifying glass and sufficient lighting. Look for dull blades, nicks, cracks, or chips. Dull blades can be recognized by the fact that they do not reflect light when illuminated directly. *Tool: Magnifying glass*

1.13

PG01	36	Extractor
36.00.00 - 36.99.99		
		Visually inspect the instruments for damaged surfaces, chipping, deformation, burrs—especially at the working end. Also check the condition of the plastic handle. If any defects are identified, the products must be discarded. *Tool: Magnifying glass*
		Check the instrument for corrosion or surface changes that could promote the formation of corrosion (e.g., yellow-brown to dark brown localized discoloration, especially in hard-to-reach areas). *Tool: Magnifying glass*
		Check blades and cutting surfaces carefully using a magnifying glass and sufficient lighting. Look for blunt tips, nicks, cracks, or chips. *Tool: Magnifying glass*

1.14

PG01	36	Tampers
36.00.00 - 36.99.99		
		Visually inspect the instruments for damaged surfaces, chipping, deformation, burrs—especially at the working end. Also check the condition of the plastic handle. If any defects are identified, the products must be discarded. *Tool: Magnifying glass*
		Check the instrument for corrosion or surface changes that could promote the formation of corrosion (e.g., yellow-brown to dark brown localized discoloration, especially in hard-to-reach areas). *Tool: Magnifying glass*