NEXON
MEDICAL

NEXON LATERAL CAGE SYSTEM

Instructions for Processing of Instruments and Care & Maintenance

INDEX

A. PURPOSE

This document contains recommendations for the safe handling, effective care, cleaning, disinfection and sterilization of Nexon Medical reusable surgical instruments, instrument trays and cases. The information provided does not apply to Nexon Medical implants.

B. INTRODUCTION

All instruments are to be cleaned, disinfected and sterilized prior to each application; this is required as well for the first use after delivery of the unsterile instruments (cleaning and disinfection after removal of the protective packaging, sterilization after packaging). An effective cleaning and disinfection is an indispensable requirement for an effective sterilization of the instruments.

You are responsible for the sterility of the instruments. Therefore, please ensure that only sufficiently device and product specifically validated procedures will be used for cleaning, disinfection, and sterilization, that the used devices (WD (Washer-Disinfector), Sterilizer) will be maintained and checked regularly, as well as that the validated parameters will be applied for each cycle.

Please pay attention to avoid a higher contamination of the complete sterilization tray during application by separate collection of contaminated instruments (without laying back into the sterilization tray). Pre-clean the contaminated instruments, clean, disinfect, then sort them back into the sterilization tray and sterilize the completely equipped sterilization tray.

Instruments shall be cleaned seperately from instruments trays and cases, also lids shall be removed from cases prior to cleaning.

Additionally, please pay attention to the legal provisions valid for your country as well as to the hygienic instructions of the hospital. This applies particularly to the different guidelines regarding the inactivation of prions.

ATTENTION: In case of some instruments additional or deviating procedures are required (see chapter D. SPECIFIC ASPECTS).

C. CLEANING AND DISINFECTION

1. BASICS

If possible, an automated procedure (WD) should be used for cleaning and disinfection of the instruments. A manual procedure – even in case of application of an ultrasonic bath – should only be used if an automated procedure is not available; in this case, the significantly lower efficiency and reproducibility of a manual procedure has to be considered[1] .

The pre-treatment step is to be performed in both cases.

2. PRE-TREATMENT

Body fluids and tissue should not be allowed to dry on instruments, please remove any impurities after application but within a maximum of 2 hours. To avoid contamination, soiled devices should be separated from non-contaminated devices.

Pay attention to the following points during selection of the cleaning detergent[2]:

- fundamental suitability for the cleaning of instruments made of metallic or plastic material
- suitability of the cleaning detergent for ultrasonic cleaning (no foam development)
- compatibility of the cleaning detergent with the instruments (see chapter C.9. MATERIAL RESISTANCE)

Pay attention to the instructions of the detergent manufacturer regarding concentration, temperature and soaking time as well as post-rinsing. Please use only freshly prepared solutions as well as only sterile or low contaminated water (max. 10 germs/ml) as well as low endotoxin contaminated water (max. 0.25 endotoxin units/ml), for example purified/highly purified water, and a soft, clean, and lint-free cloth and/or filtered air for drying, respectively.

PROCEDURE:

a Disassemble the instruments as possible (see chapter E. DISSASSEMBLY INSTRUCTION).

b Rinse the instruments at least 1 min under running water (temperature < 35 °C/95 °F). Actuate movable parts at least three times during pre-rinsing if applicable (see chapter D. SPECIFIC ASPECTS).

c Rinse all lumen of the instruments at least three times at the beginning of the soaking time.

d Soak the disassembled instruments for the given soaking time (but not less than 5 min) in the pre-cleaning solution[2] (ultrasonic bath, ultrasound not activated) so that the instruments are sufficiently covered. Pay attention that there is no contact between the instruments. Assist cleaning by careful brushing with a soft brush (at beginning of soaking, aids see chapter D. SPECIFIC ASPECTS). Actuate movable parts at least three times during pre-cleaning if applicable (see chapter D. SPECIFIC ASPECTS).

e Rinse all lumen of the instruments at least three times at the end of the soaking time.

f Activate ultrasound for an additional soaking time (but not less than 5 min).

1 In case of application of a manual cleaning and disinfection procedure a product and procedure specific validation under sole responsibility of the user is required.

2 In case of application of a cleaning and disinfection detergent for this (e.g. in consequence of personnel's safety) please consider, that this should be aldehyde-free (otherwise fixation of blood impurities), possess a fundamentally approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking), be suitable for the disinfection of instruments made of metallic or plastic material, and be compatible with the instruments (see chapter C.9. Material Resistance). Please consider, that a disinfectant used in the pre-treatment step serves only the personnel's safety, but cannot replace the disinfection step later to be performed after cleaning.

g Then, remove the instruments of the pre-cleaning solution and post-rinse them at least three times intensively (at least 1 min) with water. Actuate movable parts at least three times during post-rinsing, if applicable (see chapter D. SPECIFIC ASPECTS). Rinse all lumen of the instruments at least three times during post-rinsing.

3. AUTOMATED CLEANING / DISINFECTION

Pay attention to the following points during selection of the washer-disinfector (WD):

- fundamentally approved efficiency of the WD (for example CE marking according to EN ISO 15883 or DGHM or FDA approval/clearance/registration)
- possibility for an approved program for thermal disinfection (A0 value 3000 or – in case of older devices - at least 5 min at 90 °C/194 °F; in case of chemical disinfection – danger of remnants of the disinfectant on the instruments)
- fundamental suitability of the program for instruments as well as sufficient rinsing steps in the program
- post-rinsing only with sterile or low contaminated water (max. 10 germs/ml, max. 0.25 endotoxin units/ml), for example purified/highly purified water
- only use of filtered air (oil-free, low contamination with microorganisms and particles) for drying
- regularly maintenance and check/calibration of the WD

Pay attention to the following points during selection of the cleaning detergent:

- fundamental suitability for the cleaning of instruments made of metallic or plastic material
- additional application – in case of non-application of a thermal disinfection – of a suitable disinfectant with approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) compatible to the used cleaning detergent
- compatibility of the used detergents with the instruments (see chapter C.9. Material Resistance)

Pay attention to the instructions of the detergent manufacturers regarding concentration, temperature and soaking time as well as post-rinsing.

PROCEDURE:

a Disassemble the instruments as possible (see chapter E. DISSASSEMBLY INSTRUCTION)
b Transfer the disassembled instruments in the WD (pay attention that the instruments have no contact).
c Connect the instruments to the rinsing port of the WD if applicable (see chapter D. SPECIFIC ASPECTS)
d Start the program.
e Disconnect from rinsing port if applicable and remove the instruments of the WD after end of the program.
f Check and pack the instruments immediately after the removal ((see chapter C.4. VISUAL INSPECTION / FUNCTION TESTING, chapter E. DISSASSEMBLY INSTRUCTION, chapter C.6. PACKAGING and chapter G. PLACEMENT SPECIFICATION FOR STERILIZATION), if necessary after additional post-drying at a clean place).

4. VISUAL INSPECTION / FUNCTION TESTING
Reusable instruments shall be inspected carefully prior to sterilization for the following characteristics:

Cleanliness:	Ensure that all visible blood or other impurities have been removed.
Damage or wear:	Visually inspect for damage, including but not limited to, corrosion, damaged surfaces cracks or wear.
Functionality:	Including but not limited to sharpness of cutting devices, movement of joints and couplings (see chapter D. SPECIFIC ASPECTS)

Do not further use damaged instruments (for limitation of the numbers of re-use cycles see chapter C. 10 REUSABILITY).

Still dirty instruments are to be cleaned and disinfected again.

5. MAINTENANCE
Assemble disassembled instruments again
(see chapter E. DISSASSEMBLY INSTRUCTION).

Lubricate hinges, threads and other moving parts according to chapter E. DISSASSEMBLY INSTRUCTION. If applicating, use only instrument oils (white oil) admitted to steam sterilization, considering the maximum possible sterilization temperature and with approved biocompatibility. Do only apply a small amount to the relevant location (no spraying on the complete instrument!).

For several instruments, the use of instrument oils must not be performed (see chapter D. SPECIFIC ASPECTS).

6. PACKAGING
Insert the cleaned and disinfected instruments in the corresponding sterilization trays (see chapter G.. PLACEMENT SPECIFICATION FOR STERILIZATION) and pack them in sterilization containers, which fulfill the following requirements (material/process):

- EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)
- suitable for steam sterilization (temperature resistance up to at least 142 °C (288 °F), sufficient steam permeability)
- sufficient protection of the instruments as well as of the sterilization packaging to mechanical damage
- regular maintenance according to the instructions of the manufacturer (sterilization container)

A maximum weight of 7.6 kg per content of the sterilization container must not be exceeded.

7. STERILIZATION

Please use for sterilization of Nexon Medical devices only the listed sterilization procedures; other sterilization procedures must not be applied.

Steam sterilization

- fractionated vacuum/dynamic air removal procedure[3,4] (with sufficient product drying[5])
- steam sterilizer according to EN 13060/EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
- validated according to EN ISO 17665 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ))
- maximum sterilization temperature 138 °C (280 °F; plus, tolerance according to EN ISO 17665)
- sterilization time (exposure time at the sterilization temperature)

The following parameters are to be used for the sterilization of Nexon Medical devices with fractionated vacuum and dynamic air removal:

Area	Minimum Sterilization Exposure Time (minutes)	Minimum Sterilization Exposure Temperature	Minimum Drying Time (minutes)
USA	4	132°C (270°F)	20[5]
Germany	5[6]	134°C (273°F)	
Other countries	4	132°C (270°F) / 134°C (273°F)	

The sterilizer manufacturer's operating instructions shall be followed. When sterilizing multiple instruments in one steam sterilization cycle, ensure that the maximum sterilization load is not exceeded. Drying times will vary according to load size and should be increased for larger loads.

The sterilizer must be properly installed, calibrated, validated and maintained.

ATTENTION: Do not use dry heat sterilization, radiation sterilization, formaldehyde and ethylene oxide sterilization, flash/immediate use sterilization as well as plasma sterilization!

8. STORAGE

Packaged products should be stored in a dry, dust-free environment, protected from direct sunlight, pests and extremes of temperature and humidity.

3 At least three vacuum steps
4 The less effective gravity displacement procedure must not be used in case of availability of the fractionated vacuum procedure and requires a sterilizer, program, parameter, and product specific validation under sole responsibility of the user.
5 The effectively required drying time depends directly on parameters in sole responsibility of the user (load configuration and density, sterilizer conditions, ...) and by this is to be determined by the user. Nevertheless, drying times less than 20 min must not be applied.
6 respectively 18 min (inactivation of prions, not relevant for USA)

9. MATERIAL RESISTANCE

Please take care that the listed substances are not ingredients of the cleaning or disinfection detergent:

- organic, mineral or oxidizing acids (minimum admitted pH-value 5.5)
- strong lyes (maximum admitted pH-value 10.1, neutral/enzymatic or weak alkaline cleaner recommended)
- organic solvents (for example: acetone, ether, alcohol, benzine)
- oxidizing agents (for example: peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic, halogenated hydrocarbons
- oil (only silicone parts)

Please consider during selection of the detergents in addition, that corrosion inhibitors, neutralizing agents, and/or rinse aids may cause potential critical remnants on the instruments.

Acid neutralizing agents or rinse aids must not be applied.

Please do not clean any instruments and sterilization trays by use of metal brushes or steel wool.

Please do not expose any instruments and sterilization trays to temperatures higher than 142 °C (288 °F)!

10. REUSABILITY

The instruments can be reused – in case of adequate care and if they are undamaged and clean – for 100 reprocessing cycles, unless otherwise indicated in chapter D. SPECIFIC ASPECTS. The user is responsible for each further use as well as for the use of damaged and dirty instruments (no liability in case of disregard).

D. SPECIFIC ASPECTS

Item No.	Name	Disassemble (see chapter E)	Rinsing Volume	Brush	Pre-Treatment
700.000.010	Nexon Inserter	yes	Outer shaft: 50 ml (single use syringe)/jet pistol	Outer shaft: small brush or pipe cleaner (Ø 6 mm) Nut: shaft: small brush or pipe cleaner (Ø 9 mm) Other surfaces: Standard	Outer Shaft: Rinse and brush cannulation at least 3 times Nut: Brush holes at least 3 times
700.000.020	Nexon Inserter, angled	yes	Outer shaft: 50 ml (single use syringe)/jet pistol	Outer shaft: small brush or pipe cleaner (Ø 6 mm) Nut: shaft: small brush or pipe cleaner (Ø 9 mm) Other surfaces: Standard	Outer Shaft: Rinse and brush cannulation at least 3 times Nut: Brush holes at least 3 times
700.000.030	Handle small	n/a	50 ml (single use syringe)/jet pistol	Small brush or pipe cleaner (Ø 6 mm) Other surfaces: Standard	Rinse and brush hole at least 3 times. Actuate AO-coupling at least 3 times.
700.000.040	Handle large				
700.000.080	T-Handle				
700.000.050	Slap Hammer	n/a	n/a	Standard	Actuate weight at least 3 times during rinsing and soaking, actuate AO coupling at least 3 times
700.000.060	Slide	n/a	n/a	Standard	Check after each step for damage of coating, in case of damage discard
700.000.070	Removal Tool	n/a	n/a	Standard	Caution: sharp tip. Check if tip is not blunt or damaged, otherwise discard. Check afterwards for remaining remnants of bone or soft tissue, if so repeat step. In case of still remaining remnants, discard.
700.000.110	Nexon Puncher	n/a	n/a	Standard	Caution: Sharp tip. Check if tip is not blunt or damaged, otherwise discard
700.000.120	Nexon Puncher, angled				Check if screw driver tip is not damaged or worn, otherwise discard.
700.000.130	Nexon Screwdriver				

Automated cleaning / disinfection	Maintenance	Packaging (see chapter G)	Maximum admitted cycle number
Outer shaft: Apply to a multi-perforated rinse lance (<3 mm). Nut: Big opening vertical in small basket (removed from tray). Inner shaft: Standard	Do not lubricate	Assemble prior to placing in tray for sterilization	100
Outer shaft: Apply to a multi-perforated rinse lance (<3 mm). Nut: Big opening vertical in small basket (removed from tray). Threaded tip and ball of joint in small basket (removed from tray) Inner shaft: Standard	Lubricate ball-joint only	Assemble prior to placing in tray for sterilization	100
Apply to multi-perforated rinse lance (Ø≤5 mm). AO coupling upwards.	Lubricate AO coupling Do not apply oil on silicone	Standard	100
	Lubricate AO coupling		
Weight in end position (away from AO-coupling).	Lubricate AO coupling	Standard	100
Check after each step for damage of coating, in case of damage discard.	Do not lubricate	Standard	100
Standard	Do not lubricate	Standard	100
Standard	Do not lubricate	Standard	5
			50

Item No.	Name	Disassemble (see chapter E)	Rinsing Volume	Brush	Pre-Treatment
700.000.140	Nexon Screwdriver, angled	yes	Outer shaft: 50 ml (single use syringe)/jet pistol	Outer shaft: small brush or pipe cleaner (Ø 6 mm) Nut: shaft: small brush or pipe cleaner (Ø 9 mm) Other surfaces: Standard	Outer Shaft: Rinse and brush cannulation at least 3 times. Nut: Brush holes at least 3 times.
700.053.008 – 018	Paddle Sizer	n/a	n/a	Standard	Standard
700.100.0XX **700.150.0XX** **700.300.0XX**	Nexon Trials	n/a	5 ml (single use syringe)/jet pistol	Small brush or pipe cleaner (Ø 3 mm)	Brush all holes and slits at least 3 times, rinse all holes and slits at least 3 times.
800.000.010	Nexon Insertion Case	Separate tray from inner tray, basket and lid	n/a	Standard	Actuate all handles and locks at least 3 times.
800.000.011 **800.000.012**	Nexon Discectomy Case 1/2				
800.000.013	Nexon Paddle Sizers Case				
800.000.020	Auxiliary Bin				
800.000.030	Screw Rack				Standard
700.000.160	Penfield Long, Pull	n/a	n/a	small brush and small brush with diameter < 2 mm	Brush inside (small brush with diameter < 2 mm) and outside (standard brush) at leat 3 times.
700.000.170	Bayonetted Knife Holder			Small brush	Brush slits at least 3 times, rinse slits at least 3 times
700.000.180	Kerrison, 3 mm	yes	n/a	Small brush	Brush all holes, slits and springs at least 3 times, rinse all holes, slits and springs at least 3 times. Actuate all handles and locks at least 3 times
700.000.190	Rongeur, 3 mm				
700.000.200	Rongeur, 5 mm				
700.000.210	Rongeur, angled, 3 mm				

Automated cleaning / disinfection	Maintenance	Packaging (see chapter G)	Maximum admitted cycle number
Outer shaft: Apply to a multi-perforated rinse lance (≤5 mm) Nut: With button sidewards in small parts basket. Big opening vertical in small basket (removed from tray). Screw driver tip and ball of joint in small basket (removed from tray). Inner shaft: Standard.	Lubricate ball joint only	Assemble prior to placing in tray for sterilization	50
Standard	Do not lubricate	Standard	100
Place with slits vertical	Do not lubricate	Standard	100
Empty with opening downwards	Do not lubricate	Standard	100
Standard			
Standard	Do not lubricate	Standard	100
Place with opened shafts	Lubricate hinges	Place opened in tray for sterilization	100

Item No.	Name	Disassemble (see chapter E)	Rinsing Volume	Brush	Pre-Treatment
700.000.220	Chisel, 7 mm	n/a	n/a	Handle: Small brush	Caution: sharp tip Check if tip is not blunt or damaged, otherwise discard. Brush and rinse handle at least 3 times
700.000.230	Annulus Cutter 6x22 mm		5 ml (single use syringe)/jet pistol	Tip: pipe cleaner (Ø 5 mm) Handle: small brush or pipe cleaner (Ø 10 mm)	Caution: sharp tip. Check if tip otherwise blunt or damaged, if so, discard. Brush handle outside (standard brush) and cutter (pipe cleaner Ø = 5 mm), rinse the blind bore at the end of the grip (back-flushing with 5 ml single-use syringe and fitted cannula/jet pistol).
700.000.240	Cobb Elevator, down angled			Small brush	Caution: sharp tip. Brush handle outside (standard brush), rinse the blind bore at the end of the grip (back-flushing with 5 ml single-use syringe and fitted cannula/jet pistol).
700.000.250	Cobb Elevator, straight				
700.000.260	Ring Curette				
700.000.270	Ring Curette, angled				
700.000.280	AO-Adapter		n/a	Standard	Standard

Automated cleaning / disinfection	Maintenance	Packaging (see chapter G)	Maximum admitted cycle number
Standard			
Place with handle / stud hole facing downwards	Do not lubricate	Standard	100
Standard			

E. DISASSEMBLY INSTRUCTION

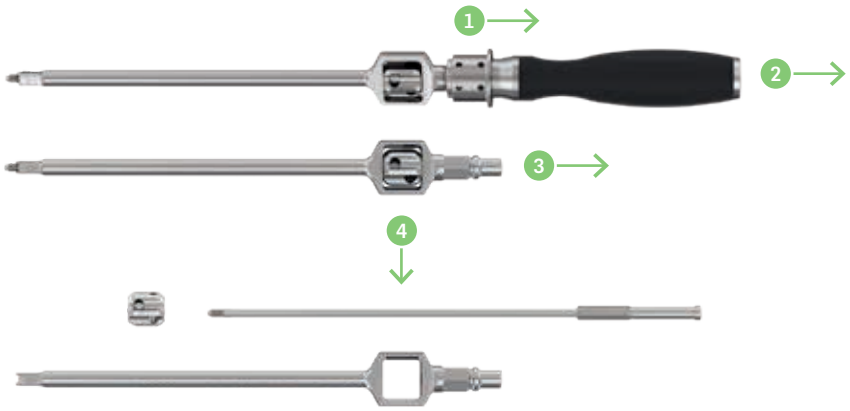
Disassembled devices might be reassembled prior to sterilization unless otherwise indicated. Check for missing parts of disassembled devices.

NOTE: If damage or wear is noticed that may compromise the function of the instrument, contact your Nexon Medical representative for a replacement.

---

1. Nexon Inserter
(700.000.010)

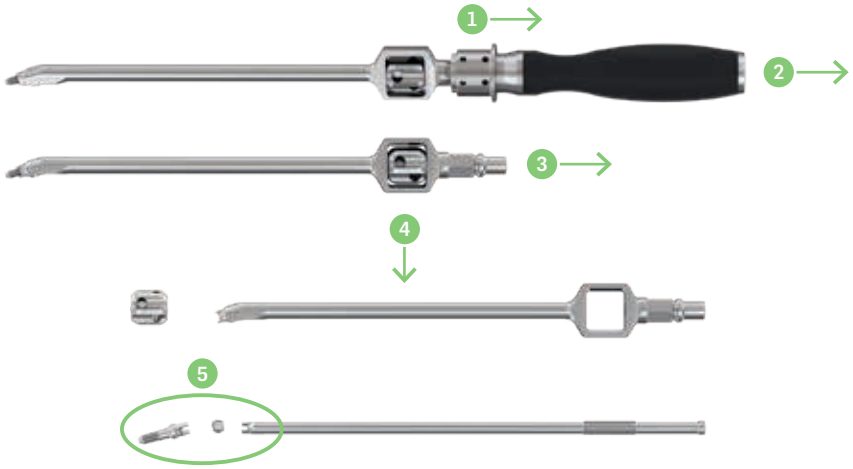
1 Pull coupling backwards
2 Remove handle
3 Remove inner shaft
4 Remove nut



---

2. Nexon Inserter, angled
(700.000.020)

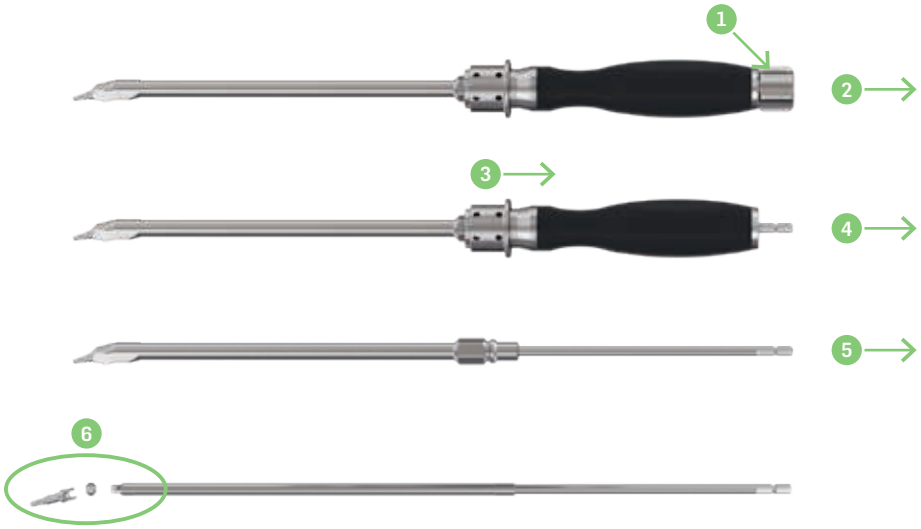
1 Pull coupling backwards
2 Remove handle
3 Remove inner shaft
4 Remove nut
5 Disassemble cardan ball joint by pulling it apart



---

3. Nexon Screwdriver, angled
(700.000.140)

1 Push button
2 Remove nut
3 Pull coupling backwards
4 Remove handle
5 Remove inner shaft
6 Disassemble cardan ball joint by pulling it apart



4. Kerrison, 3 mm
(700.000.180)

1 Squeeze handle to closed position
2 Hold closed position and turn lock upwards to unlock
3 Release handle when lock is in unlocked position
4 Lift up upper leg of Kerrison

NOTE: Sterilze in disassembled state

5. Rongeur, 3 mm, 5 mm and angled
(700.000.190, 700.000.200 and 700.000.210)

1 Squeeze handle to closed position
2 Hold closed position and turn lock upwards to unlock
3 Release handle when lock is in unlocked position
4 Lift up upper leg of Rongeur

NOTE: Sterilze in disassembled state

F. ASSEMBLY INSTRUCTION

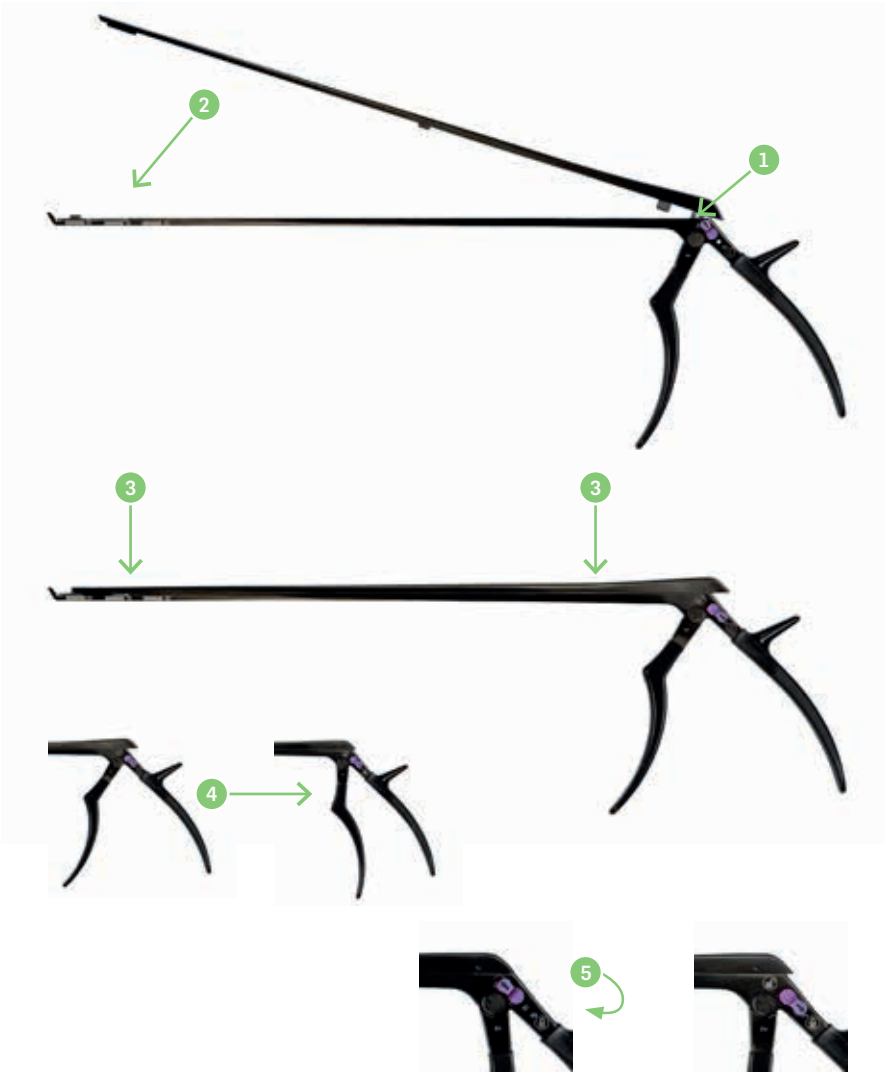
Disassembled devices might be reassembled prior to sterilization unless otherwise indicated.
Check for missing parts prior to assembling. To assemble the instrument, follow the assembly instructions below.

NOTE: If not described below, follow the disassembling instructions backwards.

---

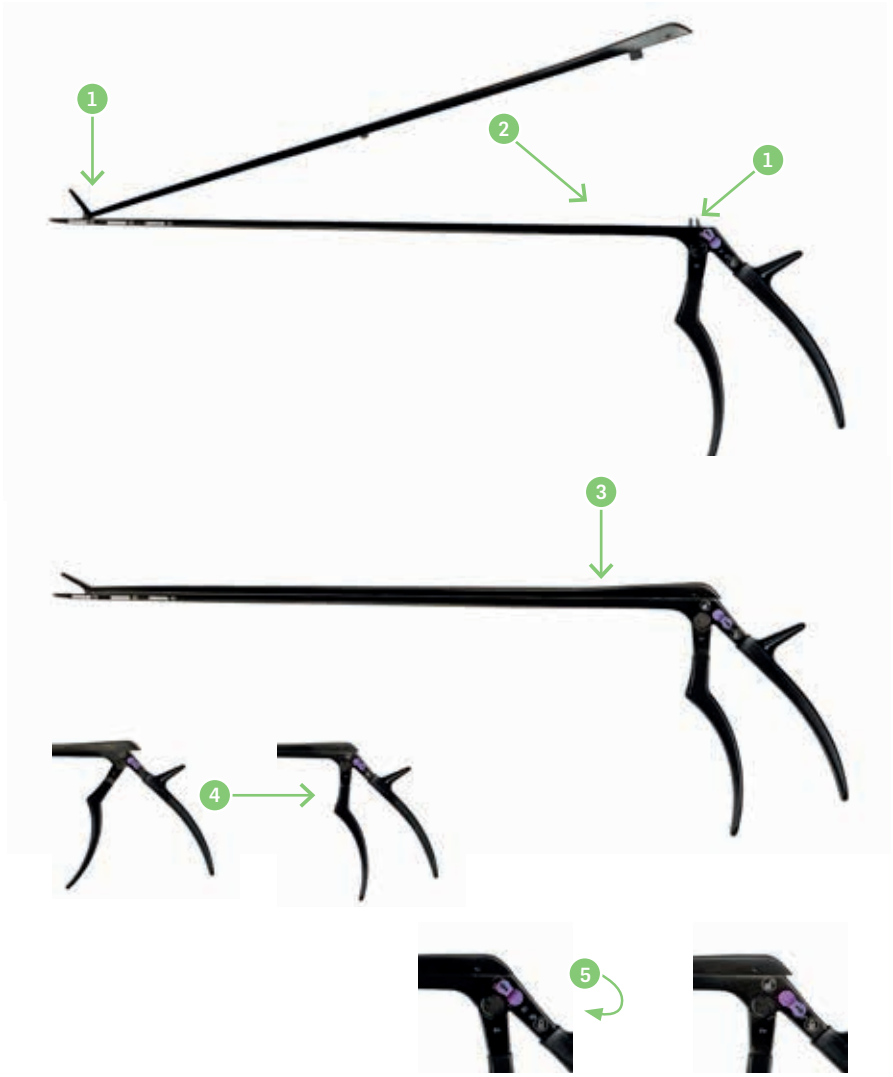
1. Kerrison, 3 mm
(700.000.180)

1 Oil joints and fits prior to assembly
2 Lower upper leg of Kerrison
3 Apply pressure on upper leg as indicated by the arrows and hold
4 Squeeze handle to closed position
5 Hold closed position and turn lock downwards to lock



2. Rongeur, 3 mm, 5 mm and angled
(700.000.190, 700.000.200 and 700.000.210)

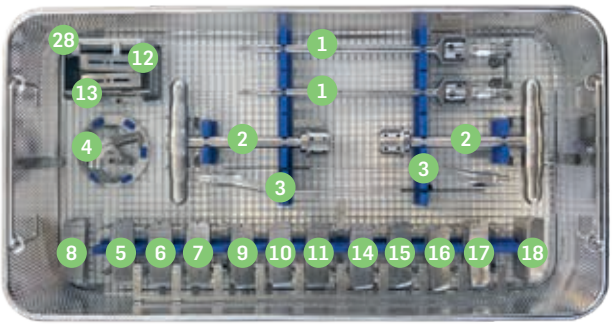
1 Oil joints and fits prior to assembly
2 Lower upper leg of Rongeur
3 Apply pressure on upper leg as indicated by the arrows and hold
4 Squeeze handle to closed position
5 Hold closed position and turn lock downwards to lock

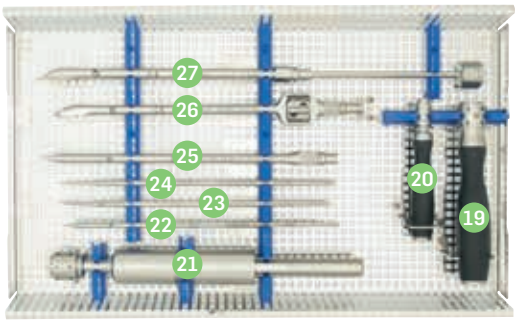


G. PLACEMENT SPECIFICATION FOR STERILIZATION

Place the assembled instruments in the case according to the pictures and tables below.

NEXON SYSTEM – CAGE INSERTION



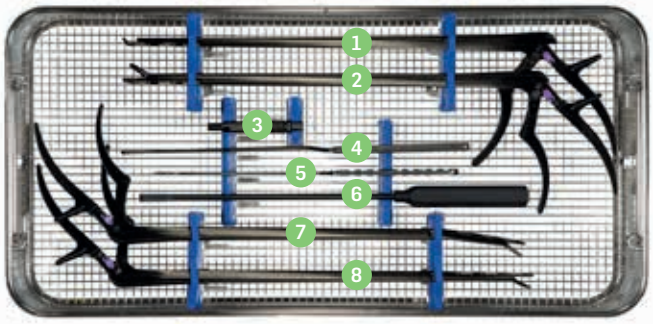


Pos.	Item No.	Name
1	700.000.010	Nexon Inserter
2	700.000.080	T-Handle
3	700.000.060	Slide
4	800.000.030	Screw Rack
5	700.100.008	Nexon Trial H08 mm, 10°
6	700.100.010	Nexon Trial H10 mm, 10°
7	700.100.012	Nexon Trial H12 mm, 10°
8	700.100.014	Nexon Trial H14 mm, 10°
9	700.150.008	Nexon Trial H08 mm, 15°
10	700.150.010	Nexon Trial H10 mm, 15°
11	700.150.012	Nexon Trial H12 mm, 15°
12	700.150.014	Nexon Trial H14 mm, 15°
13	700.150.016	Nexon Trial H16 mm, 15°
14	700.300.014	Nexon Trial, hyperlordotic H14 mm, 30°
15	700.300.016	Nexon Trial, hyperlordotic H16 mm, 30°
16	700.300.018	Nexon Trial, hyperlordotic H18 mm, 30°
17	700.300.020	Nexon Trial, hyperlordotic H20 mm, 30°
18	700.300.022	Nexon Trial, hyperlortdotic H22 mm, 30°

Pos.	Item No.	Name
19	700.000.040	Handle, large
20	700.000.030	Handle, small
21	700.000.050	Slap Hammer
22	700.000.130	Nexon Screw Driver
23	700.000.120	Nexon Puncher, angled
24	700.000.110	Nexon Puncher
25	700.000.070	Removal Tool
26	700.000.020	Nexon Inserter, angled
27	700.000.140	Nexon Screw Driver, angled
28	800.000.020	Basket for small parts (spheres, tips)

Place the assembled instruments in the case according to the pictures and tables below.

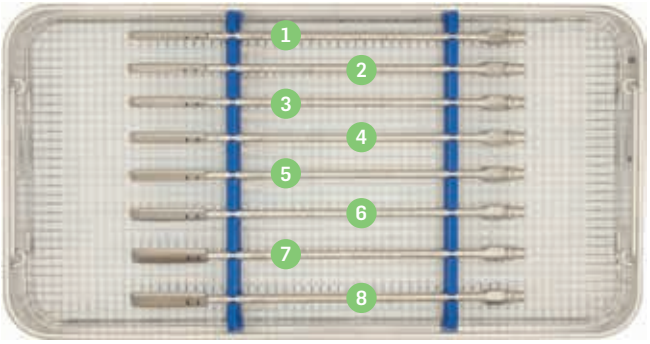
NEXON SYSTEM – DISCECTOMY INSTRUMENTS



Pos.	Item No.	Name
1	700.000.180	Kerrison, 3 mm
2	700.000.200	Rongeur, 5 mm
3	700.000.280	AO-Adapter
4	700.000.160	Penfield Long, pull
5	700.000.170	Bayonetted Knife Holder
6	700.000.220	Chisel, 7 mm
7	700.000.210	Rongeur, angled, 3 mm
8	700.000.190	Rongeur, 3 mm

Pos.	Item No.	Name
9	700.000.260	Ring Curette
10	700.000.270	Ring Curette, angled
11	700.000.230	Annulus Cutter 6x22 mm
12	700.000.240	Cobb Elevator, down angled
13	700.000.250	Cobb Elevator, straight

NEXON SYSTEM – PADDLE SIZERS



Pos.	Item No.	Name
1	700.053.008	Nexon Cage Paddle Sizer, H8
2	700.053.009	Nexon Cage Paddle Sizer, H9
3	700.053.010	Nexon Cage Paddle Sizer, H10
4	700.053.011	Nexon Cage Paddle Sizer, H11

Pos.	Item No.	Name
5	700.053.012	Nexon Cage Paddle Sizer, H12
6	700.053.014	Nexon Cage Paddle Sizer, H14
7	700.053.016	Nexon Cage Paddle Sizer, H16
8	700.053.018	Nexon Cage Paddle Sizer, H18

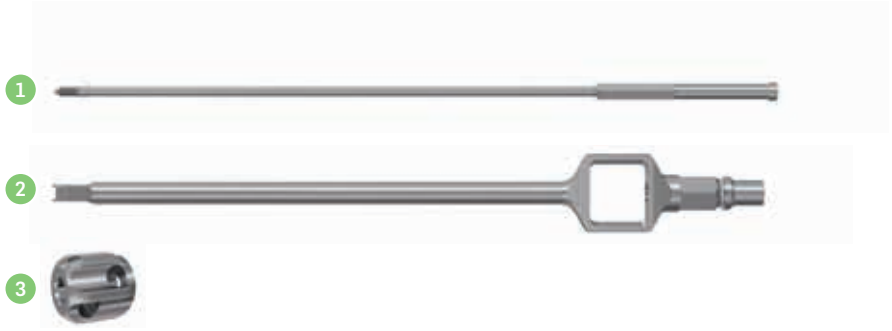
H. SPARE PARTS

Description of spare parts and article numbers. Shown are the disassembled instruments for the implantation of the Nexon Cage with their article number and name.

---

1. Nexon Inserter (700.000.010)

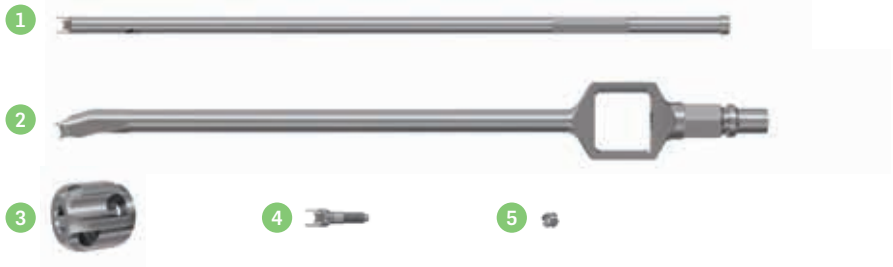
1 Nexon Inserter – inner shaft (700.000.011)
2 Nexon Inserter – outer shaft (700.000.012) Marked with superior instrument number 700.000.010
3 Nut (700.000.013)



---

2. Nexon Inserter, angled (700.000.020)

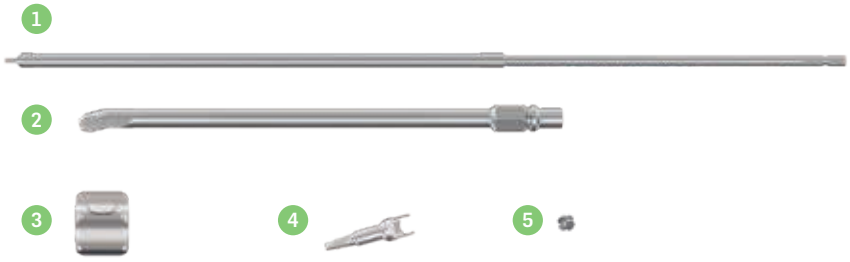
1 Nexon Inserter, angled – inner shaft (700.000.023)
2 Nexon Inserter, angled – outer shaft (700.000.024) Marked with superior instrument number 700.000.020
3 Nut (700.000.013)
4 Nexon Inserter, angled – threaded tip (700.000.021)
5 Nexon cardan sphere (700.000.022)



---

3. Nexon Screwdriver, angled (700.000.140)

1 Nexon Screwdriver, angled – inner shaft (700.000.143)
2 Nexon Screwdriver, angled – outer shaft (700.000.144) Marked with superior instrument number 700.000.140
3 Nexon Screwdriver, angled – nut (700.000.145)
4 Nexon Screwdriver, angled – tip (700.000.141)
5 Nexon cardan sphere (700.000.022)



I. ADDITIONAL INFORMATION

The instructions provided above have been validated by Nexon Medical as being capable of preparing reusable surgical instruments.

An independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory demonstrated the fundamental suitability of the instruments for an

- EFFECTIVE AUTOMATED CLEANING AND DISINFECTION by application of the WD G 7836 CD, Miele & Cie. GmbH & Co., Gütersloh, (thermal disinfection) and the pre-cleaning and cleaning detergent Neodisher Mediclean (Dr. Weigert GmbH & Co. KG, Hamburg) considering to the specified procedure.
- EFFECTIVE STEAM STERILIZATION by application of the steam sterilizer HST 6x6x6 (Zirbus technology GmbH, Bad Grund) and the fractionated vacuum/ dynamic air removal procedure.

For this, typical conditions in clinic as well as the specified procedure were considered.

It is the responsibility of the processor to ensure that reprocessing is performed using the appropriate equipment and materials and that personnel in the reprocessing facility has been adequately trained in order to achieve the desired results. This normally requires validation and routine monitoring of the process. Any deviation by the processor from these instructions should be properly evaluated for effectiveness to avoid potential adverse consequences.

Please ensure latest revision of Care & Maintenance Instruction available at www.nexonmedical.ch/eifu

J. CUSTOMER SERVICE

For further information, please contact:

NEXON MEDICAL AG
Hauptstrasse 75
6260 Reiden / Switzerland
Tel. +41 62 758 16 16
Fax +41 62 758 16 18
info@nexonmedical.ch

Notes

901.000.301 / 09-2020 / V5.0

NEXON
MEDICAL

NEXON MEDICAL AG
Hauptstrasse 75
6260 Reiden / Switzerland
Tel. +41 62 758 16 16
Fax +41 62 758 16 18
info@nexonmedical.ch
www.nexonmedical.ch