

Reprocessing Basics of Heat Stable Medical Devices

Hygiene & Reprocessing Training Material

Start >

Disclaimer

This Training Material is a summary of the steps necessary to properly reprocess heat stable medical devices. Always follow the detailed steps instructed in the latest INSTRUCTION FOR USE (REPROCESSING MANUAL).

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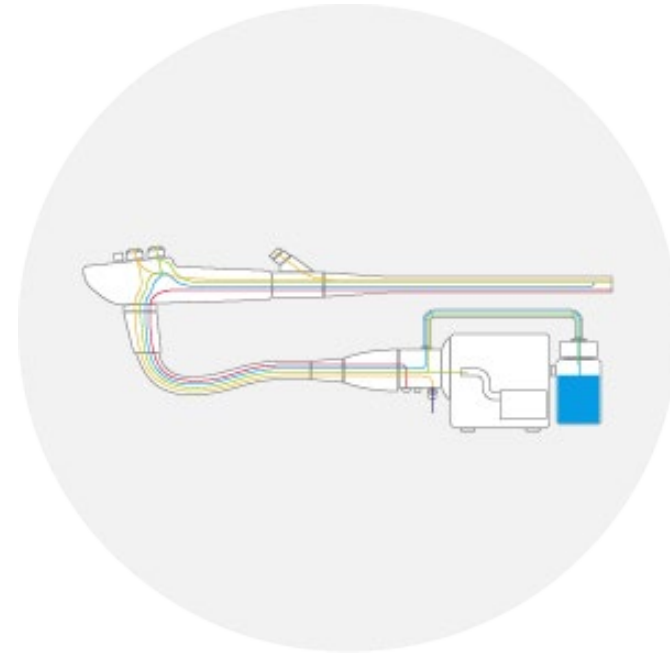
Click on the „I agree“-button to start



Prerequisites



Knowledge of relevant reprocessing steps depending on medical device and its field of application



Knowledge of Instruments' design

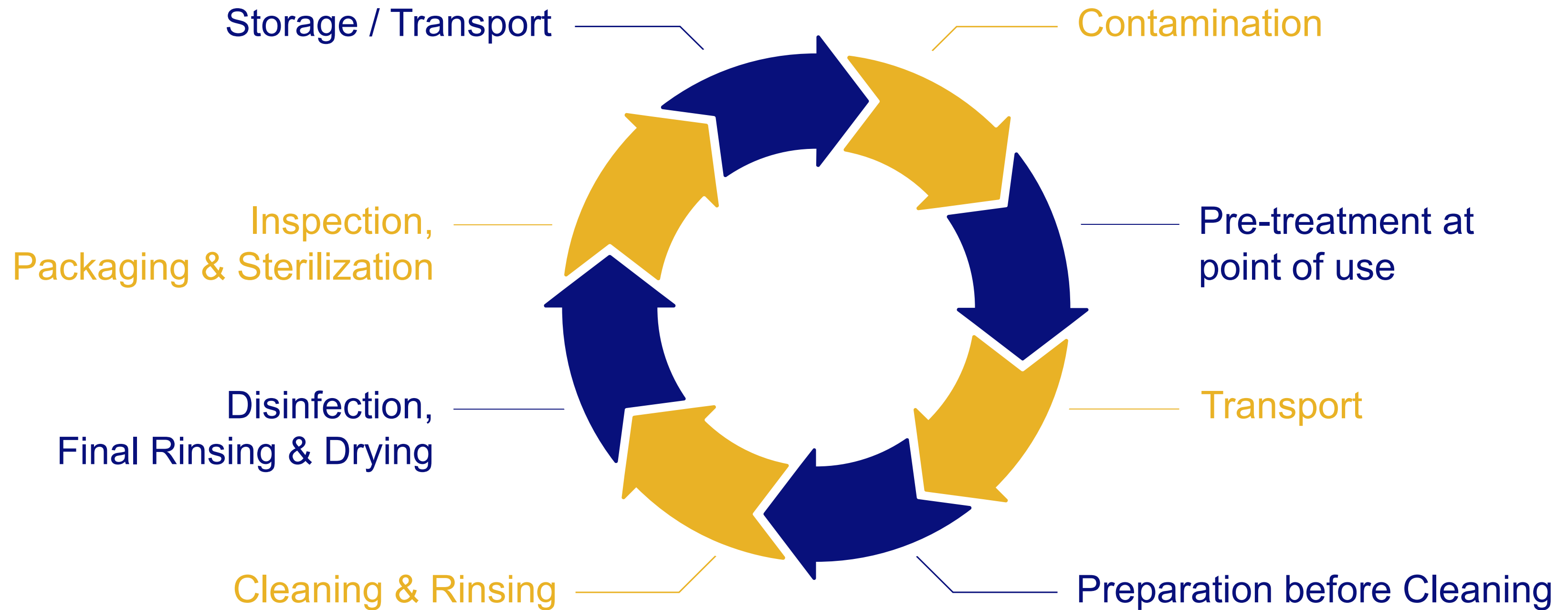


Personal protective equipment (PPE)



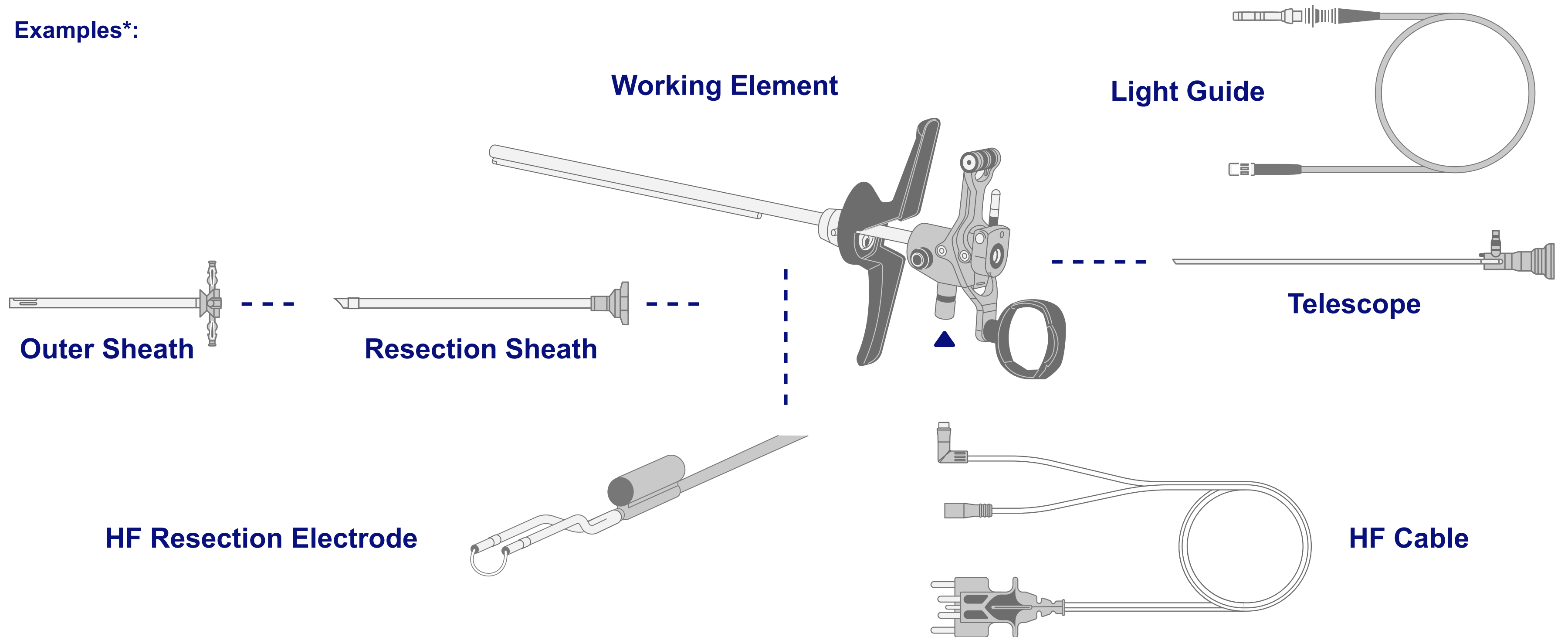
Appropriate reprocessing equipment

Reprocessing Cycle for Medical Devices | EN ISO 17664



Prerequisites | Instruments' Design

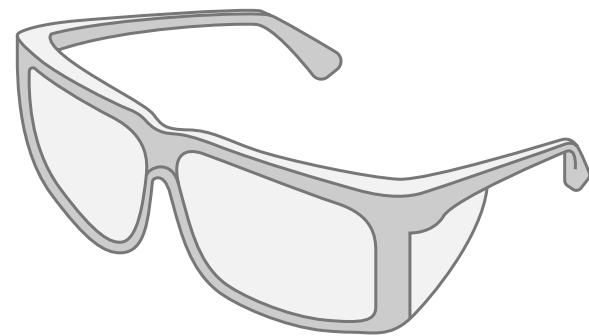
Examples*:



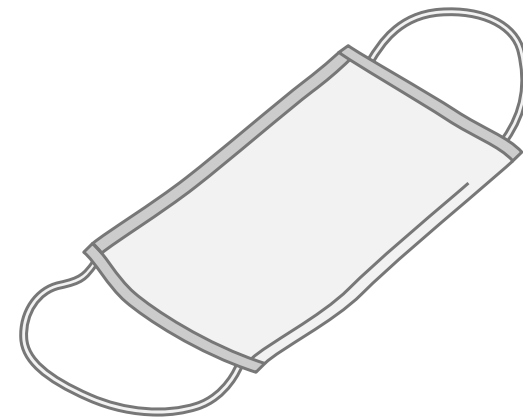
*Source: Olympus

Prerequisites | Personal Protective Equipment

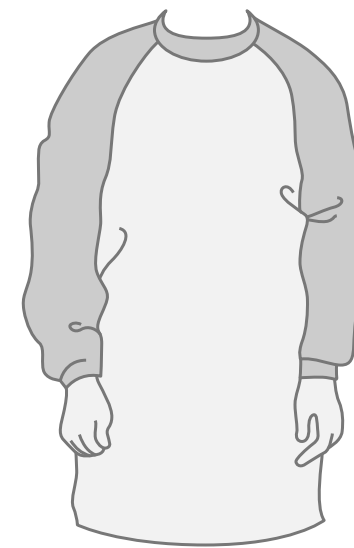
Examples*:



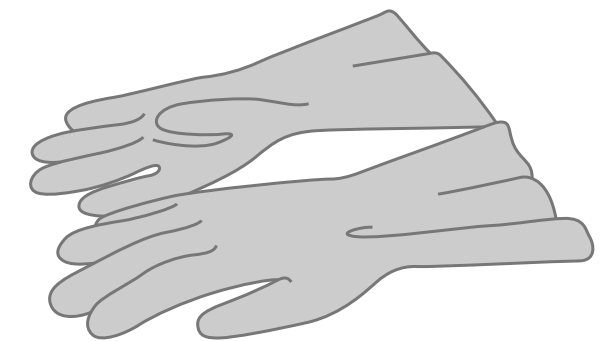
Eyewear



Face mask



Moisture-resistant clothing

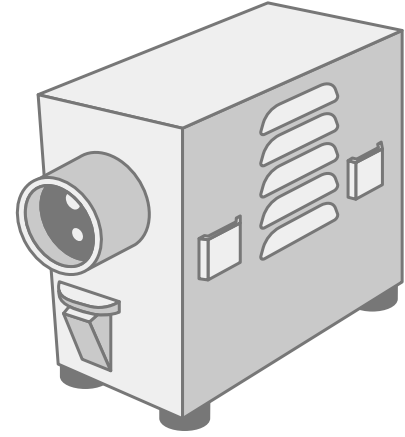


Chemical-resistant gloves

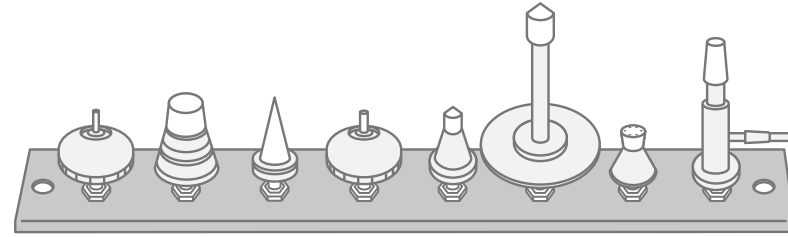
*Source: Olympus

Prerequisites | Appropriate Reprocessing Equipment

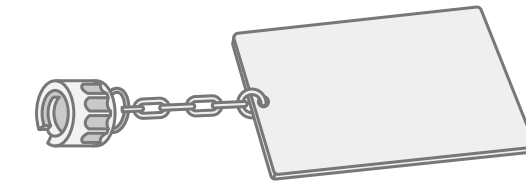
Examples*:



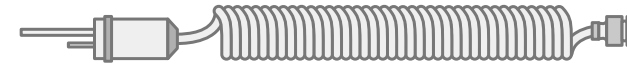
Maintenance Unit



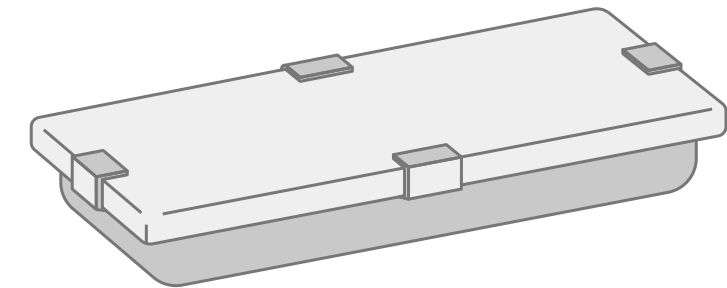
**Cleaning Pistol with
different attachments**



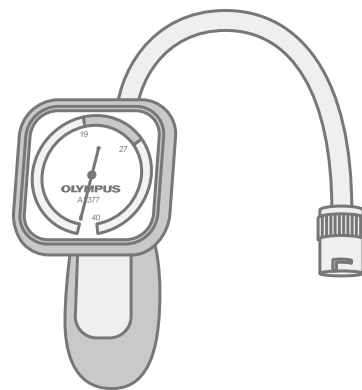
ETO Cap



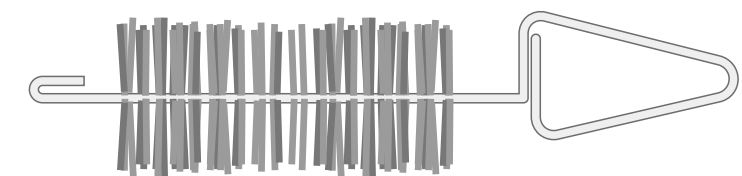
Leakage Tester



Sterilization Tray



Leakage Tester



Cleaning Brush

*Source: Olympus

Manual Cleaning of Heat Stable Medical Devices

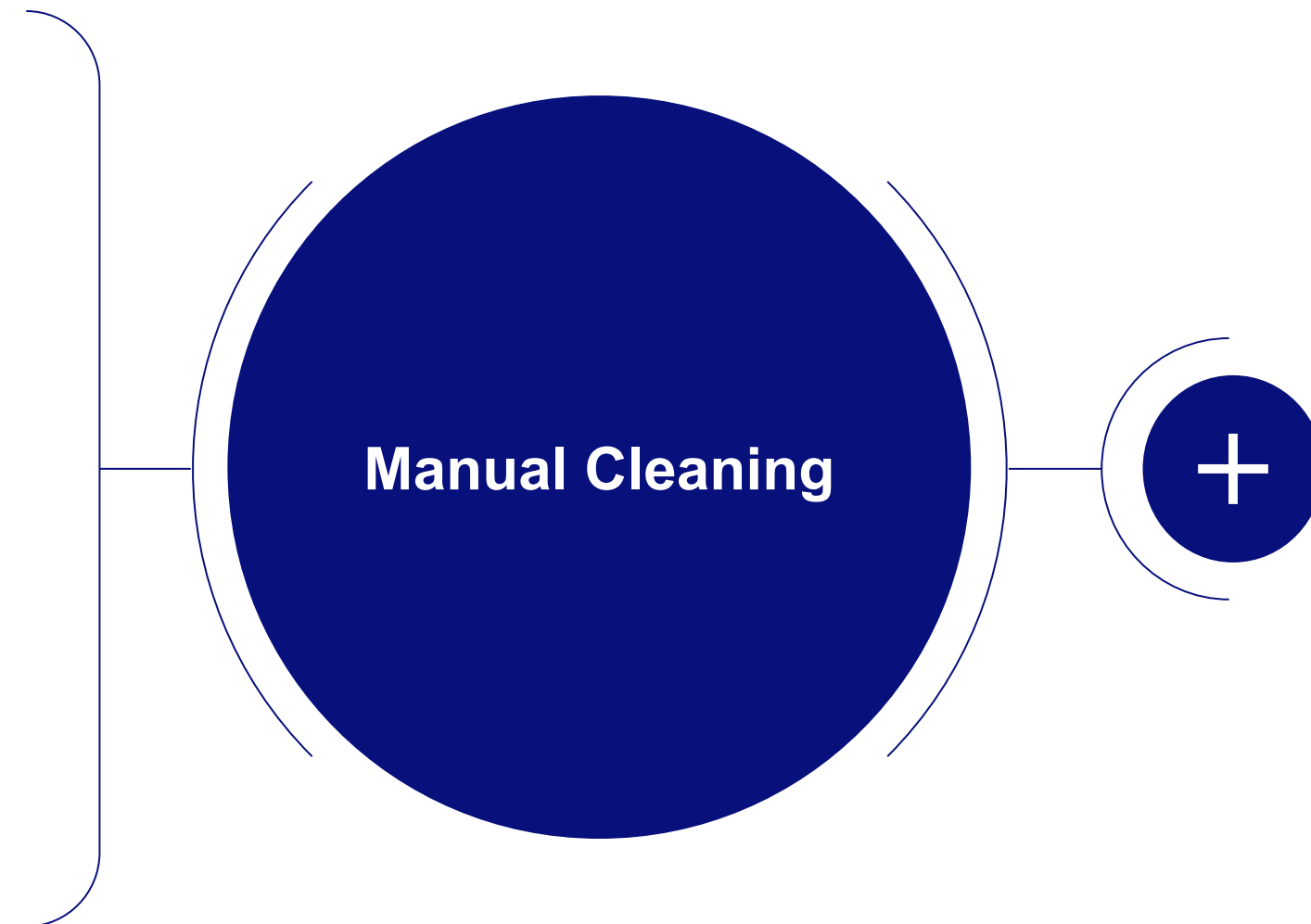


Click on the Plus-Symbols
for further information

Manual Cleaning of Heat Stable Medical Devices

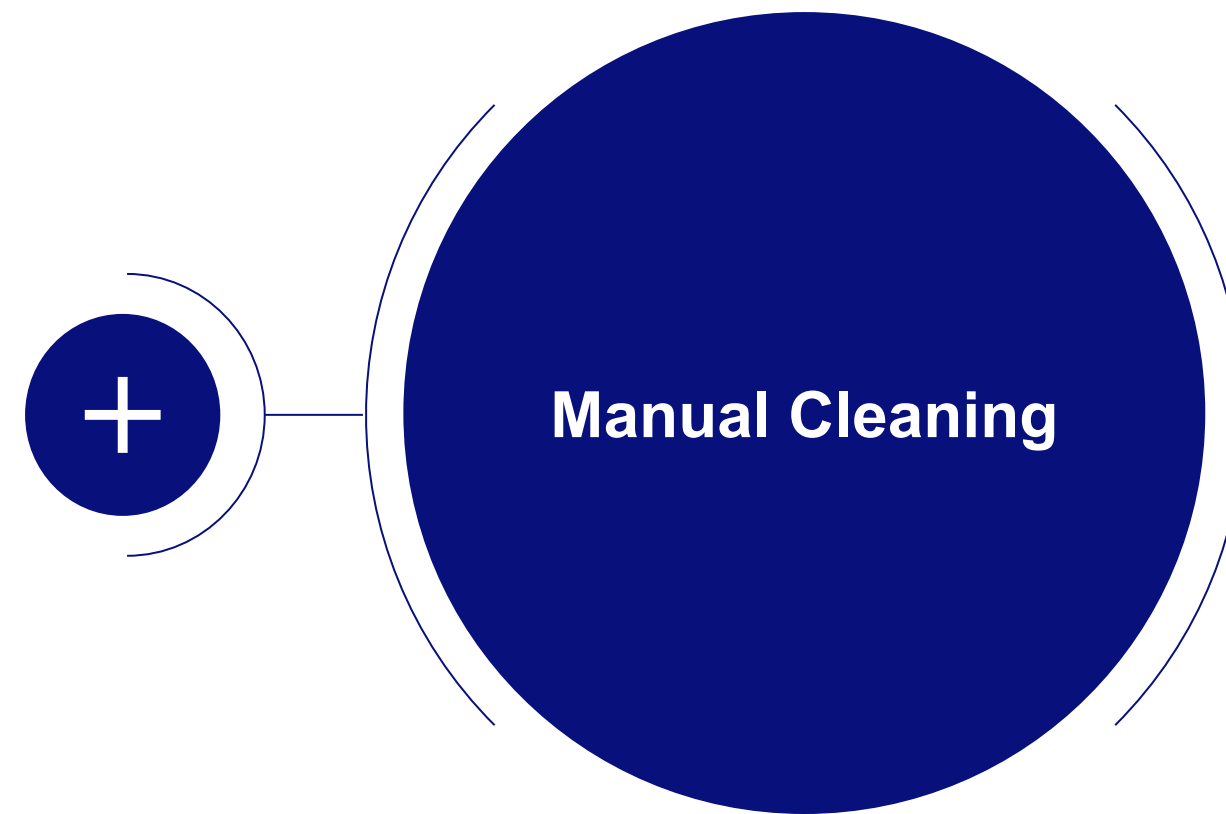
Purpose

- Removal of most microorganisms and residues, such as:
 - Fluids
 - Blood, mucus, faeces
 - Debris
 - Pharmacological substances (e.g. contrast agents, lubricants)



Click on the Plus-Symbols for further information

Manual Cleaning of Heat Stable Medical Devices

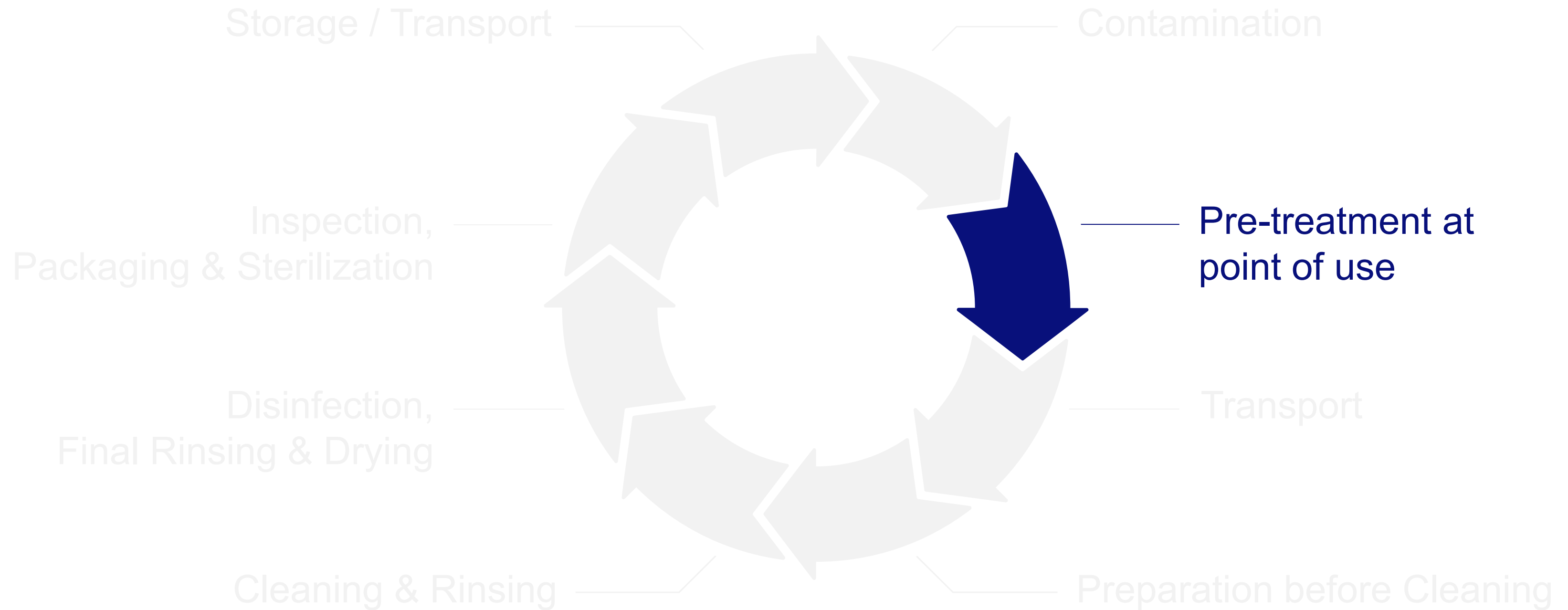


Cleaning Solutions

- Surfactants, low-foaming substances, with/without enzymes, neutral or alkaline pH (see IfU)
 - Whenever possible alkaline cleaner
- Without fixative properties (e.g. aldehydes, alcohols, peracetic acids)
- Change at least every working day; immediately in case of visible contamination
- No internationally standardized efficacy requirements for cleaners

Click on the Plus-Symbols for further information

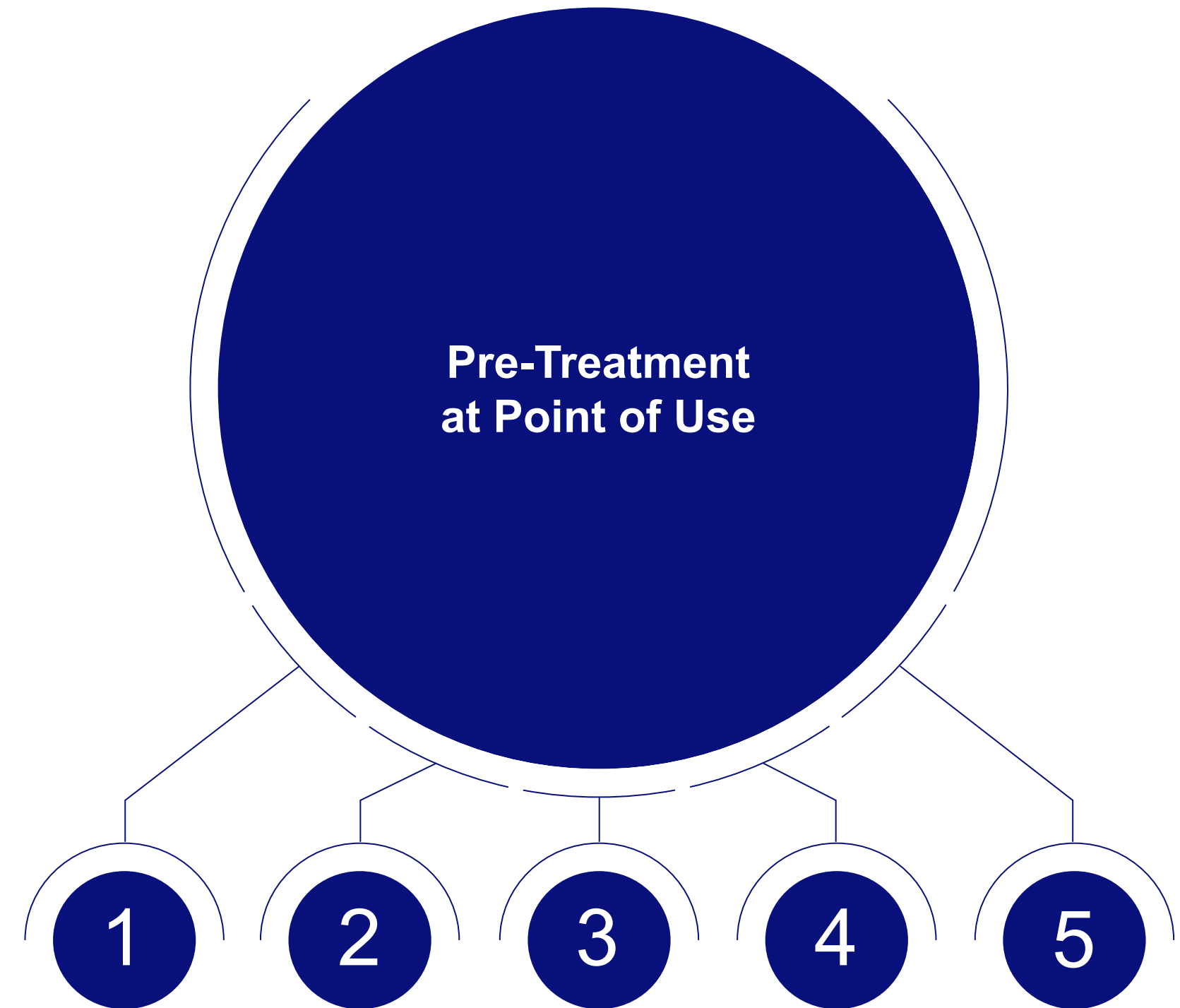
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Pre-Treatment at Point of Use

Immediately after use

- Remove gross contamination
- Disassemble the product to the extent possible
- Open jaws where present
- Unused instruments are treated like being used
- Comply with the time between use and reprocessing

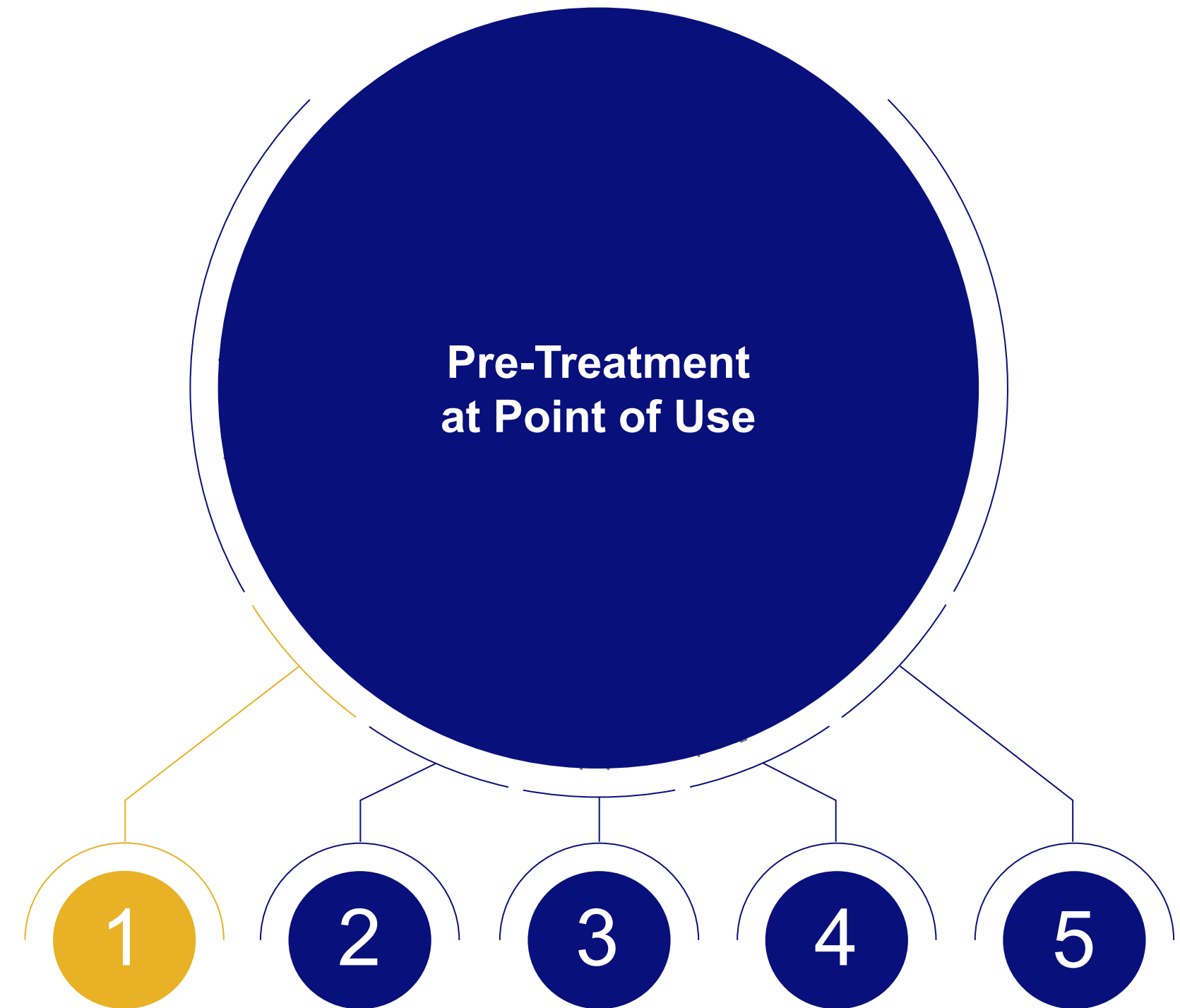


Click on the buttons for further information.

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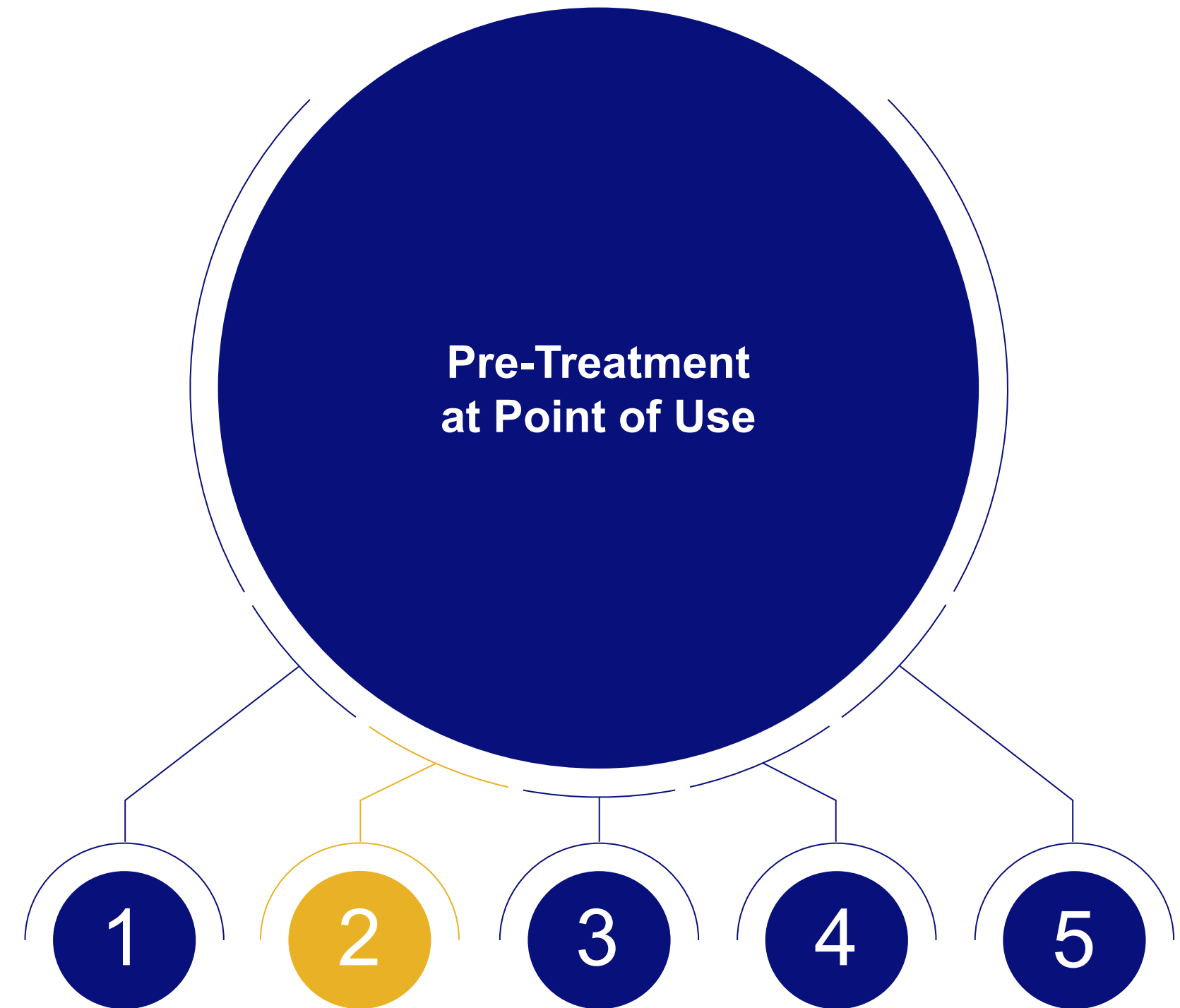
Click on the buttons for further information.

Pre-Treatment at Point of Use

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Click on the buttons for further information.

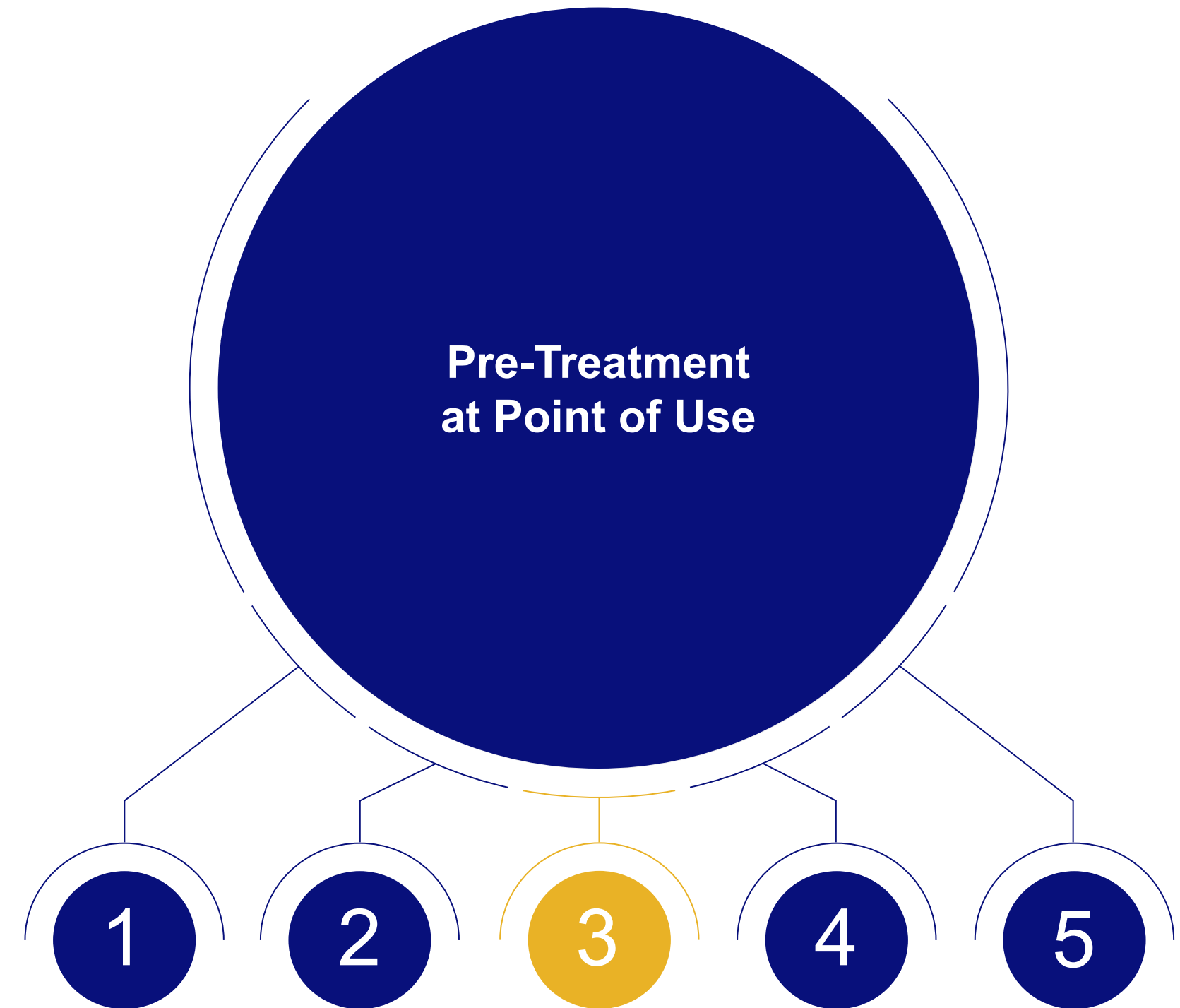


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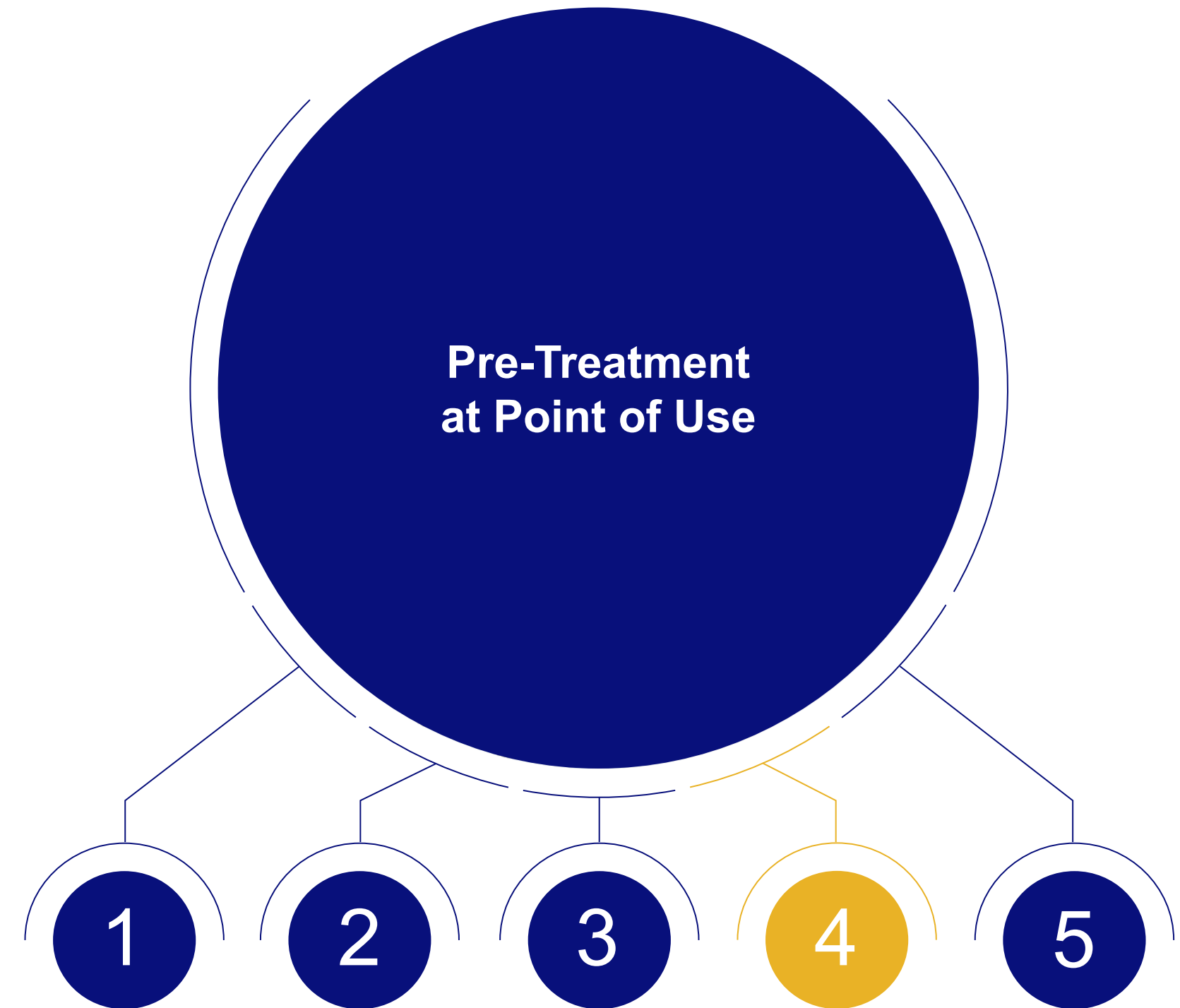


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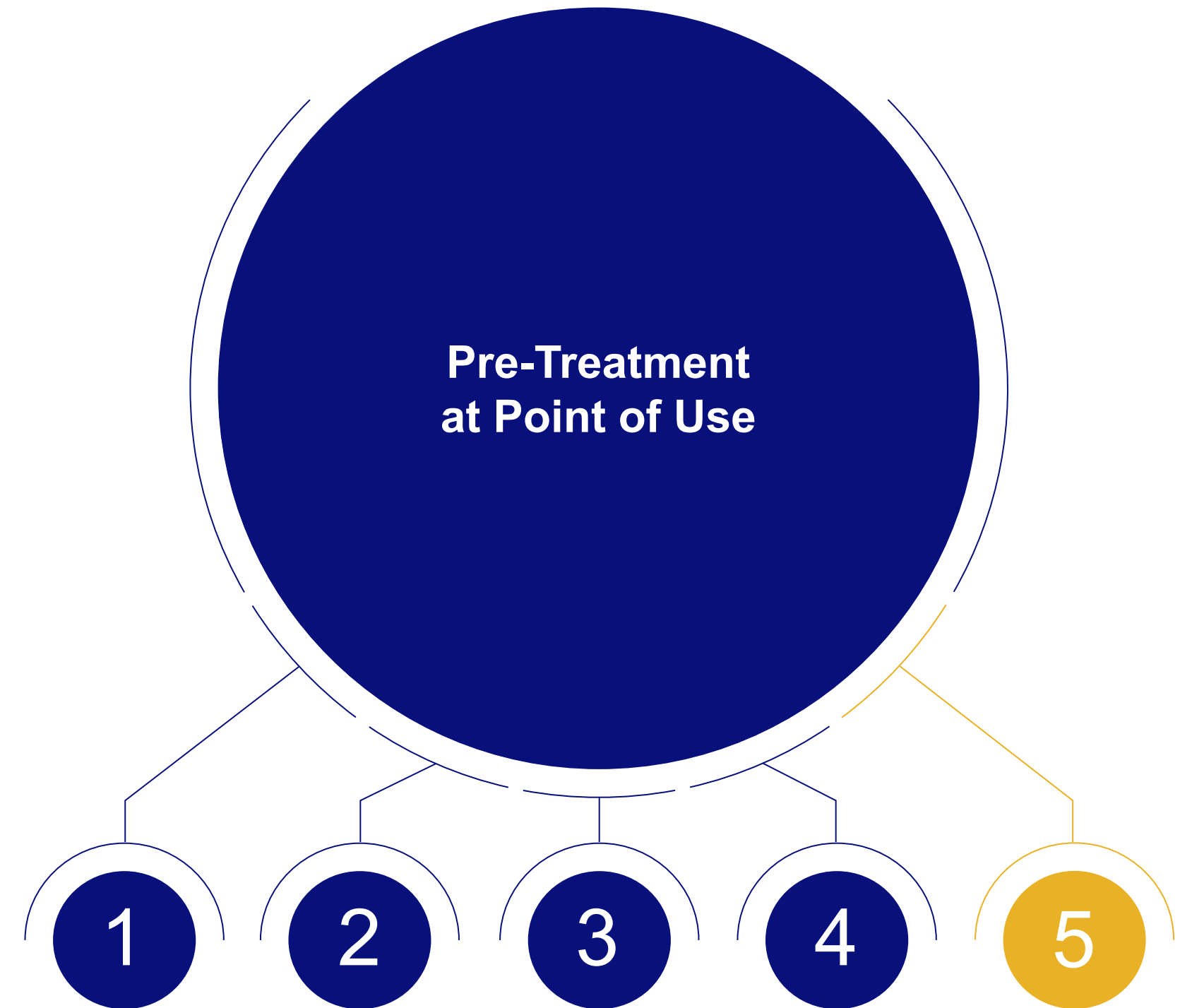


Pre-Treatment at Point of Use

Immediately after use

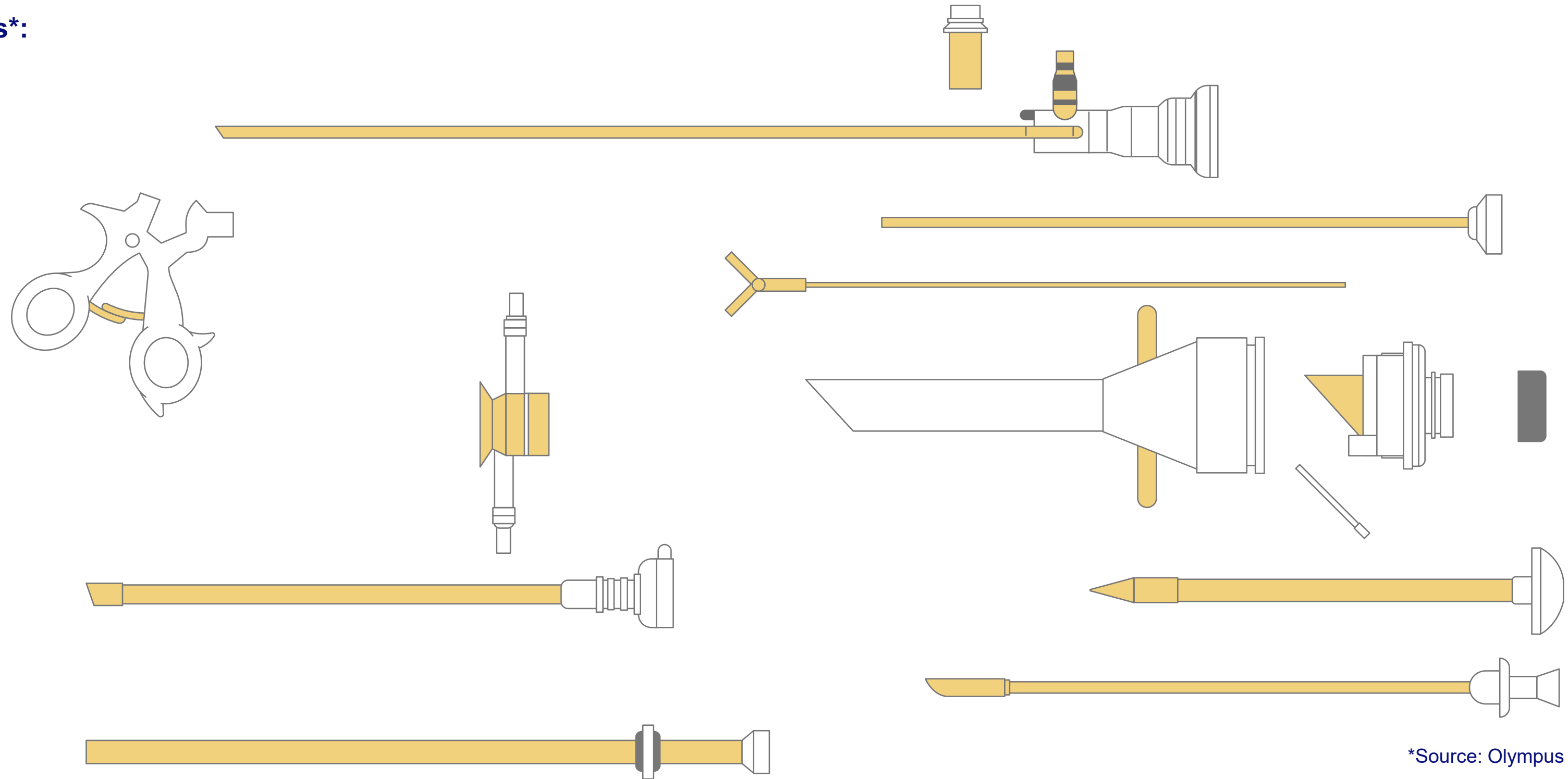
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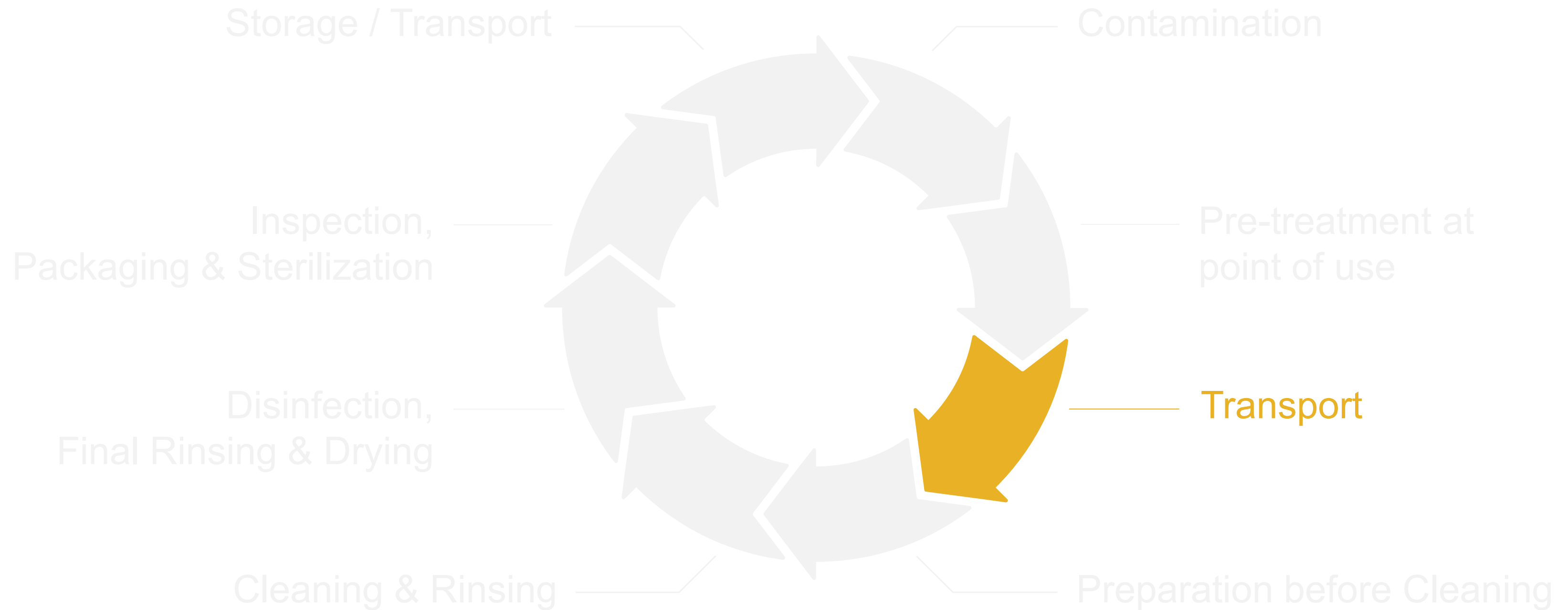
Pre-Treatment at Point of Use

Examples*:

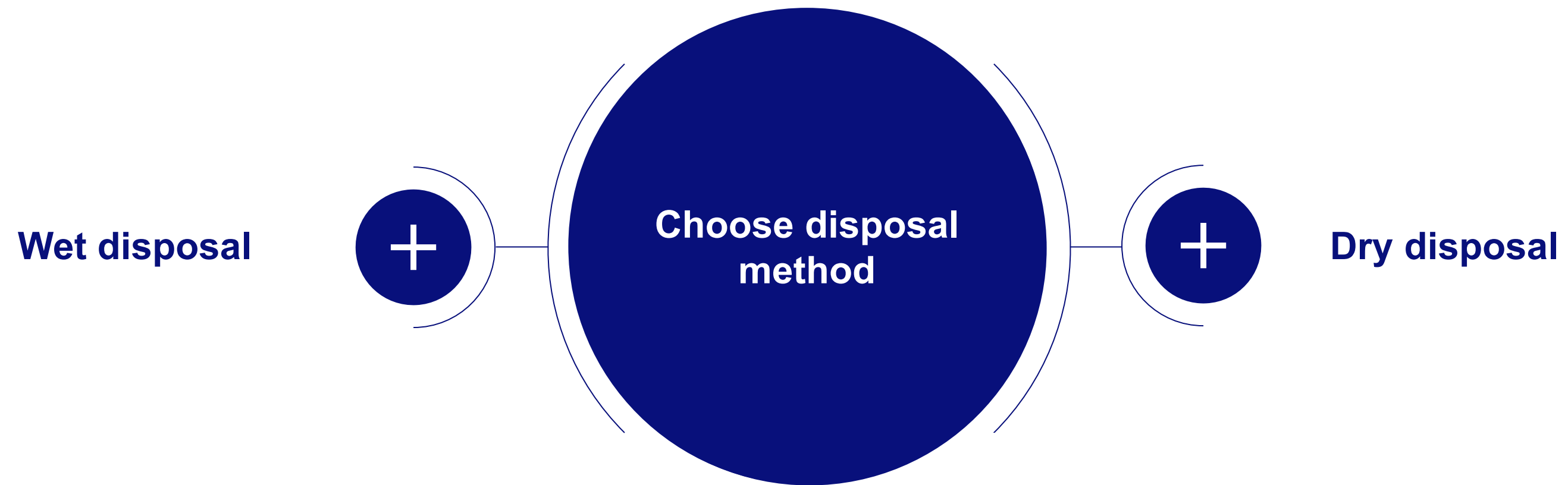


*Source: Olympus

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Transport



Click on the Plus-Symbols
for further information



Use Closed Containers
Do not overload trays

Transport

WET disposal

- Work safety
 - No long transportations
 - No risk of injury
- Avoidance of corrosion by chlorides (blood)
 - do not use physiological saline solution
- Also: “humid” disposal
 - “wrap” in moistened cloths
- When using cleaning or disinfecting solutions, strictly follow the manufacturer’s specification on temperature, immersion time and concentration

Click on the plus button for further information

Example*:



*Source: Olympus

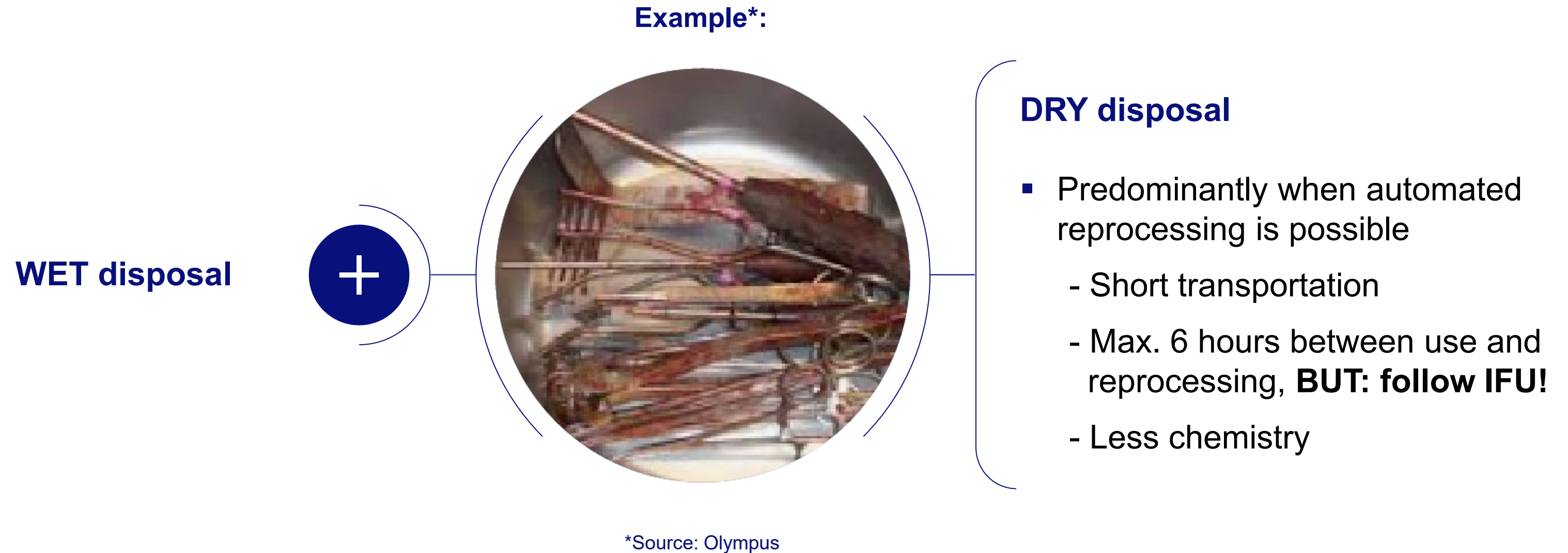
+

DRY disposal



**Use Closed Containers
Do not overload trays**

Transport

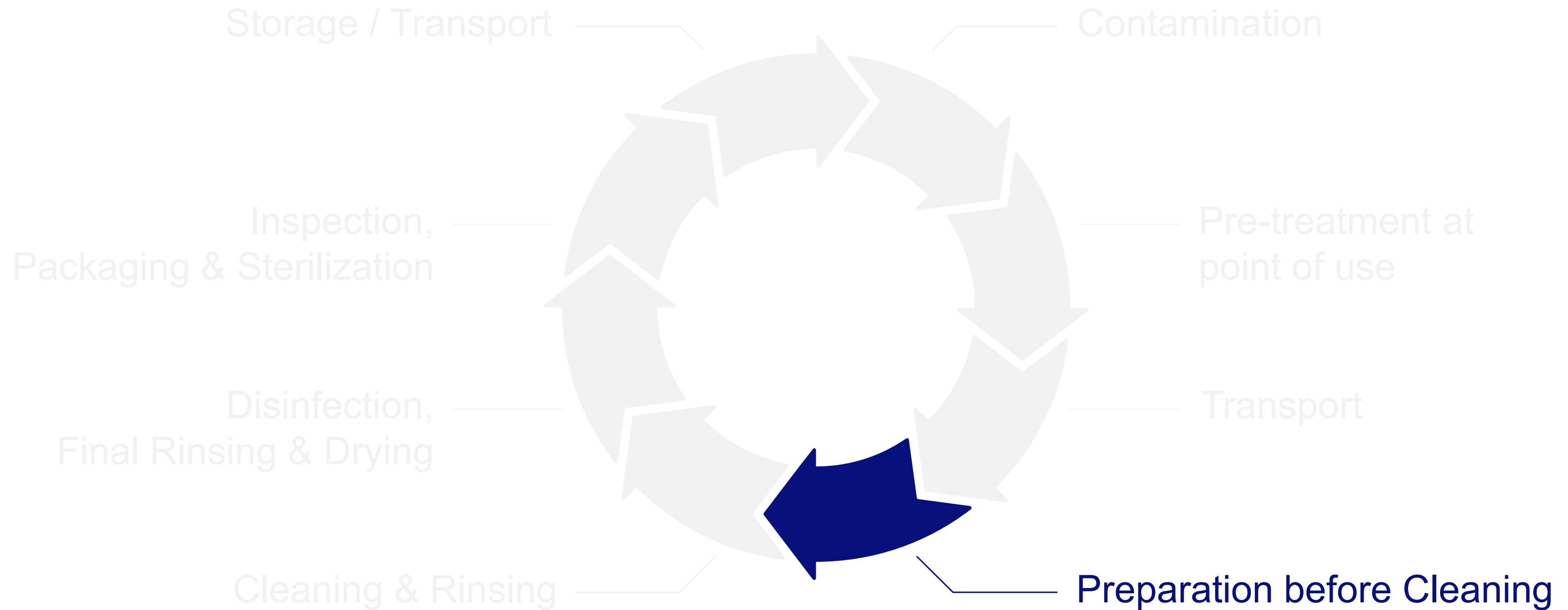


Click on the Plus-Symbols for further information



Use Closed Containers
Do not overload trays

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Preparation before Cleaning

- Disassembling, if not already done
- Depending on the design/application of a medical device, manual cleaning before WD processing not mandatory in CSSD (Central Sterile Services Department)

Can be justified by:

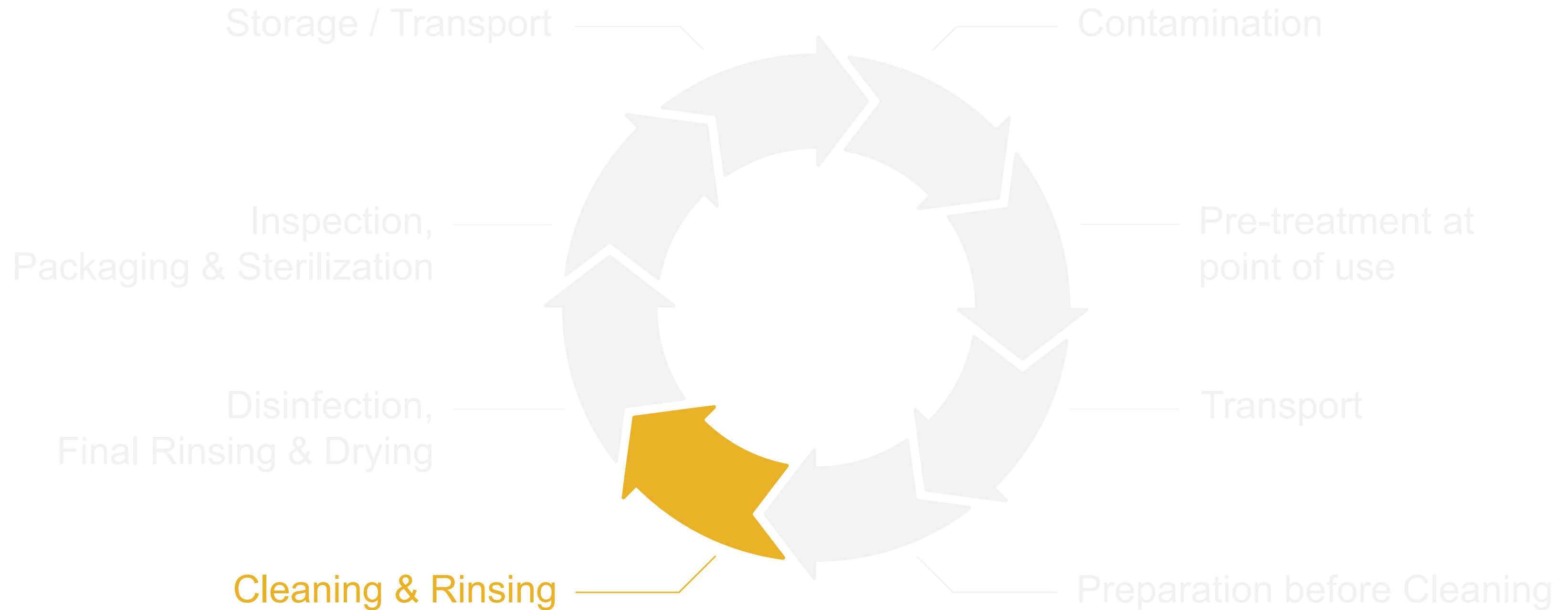
- Manufacturers' specification
- Kind and degree of soiling

Example*:



*Source: Olympus

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Cleaning & Rinsing

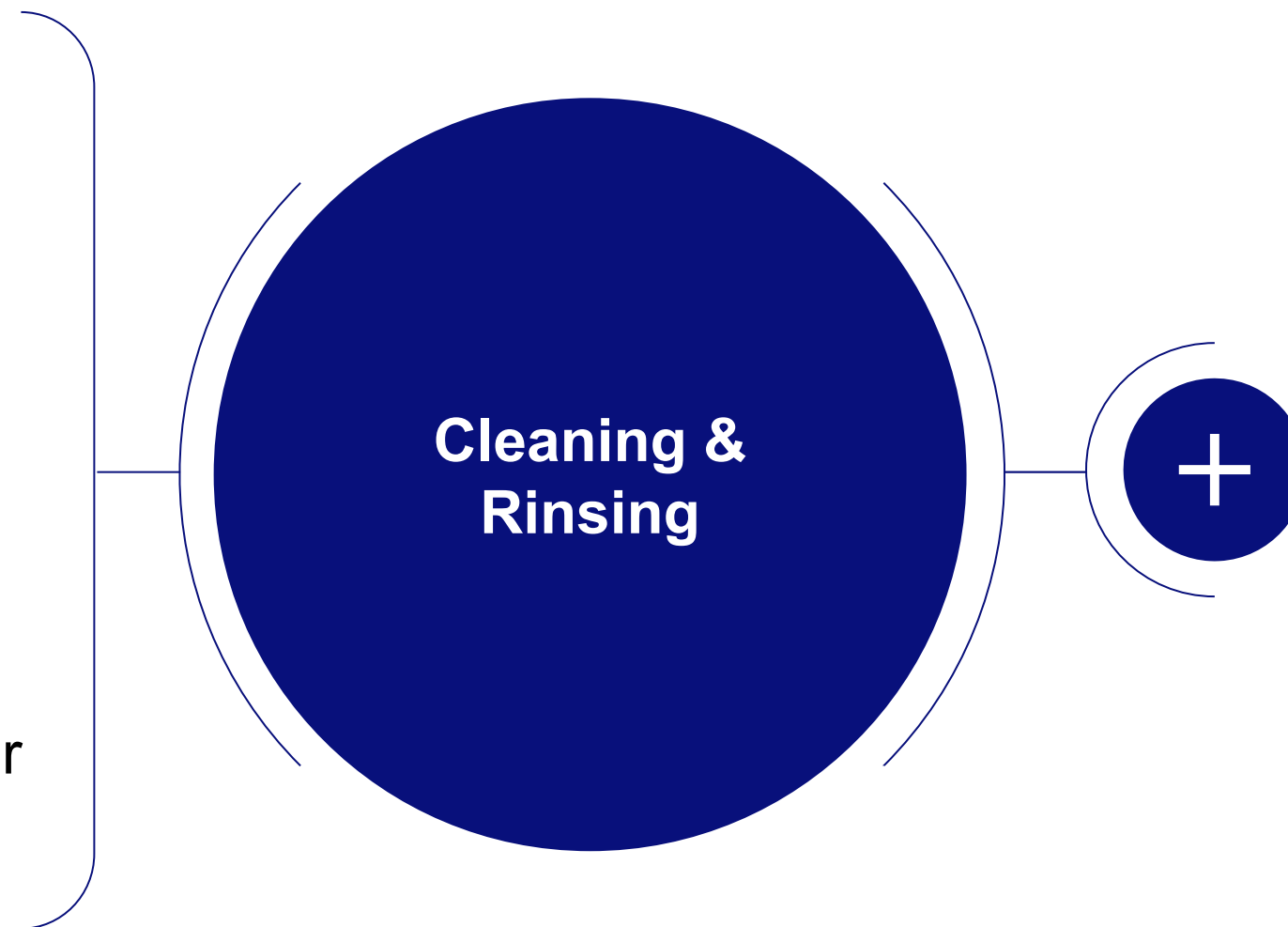


Click on the Plus-Symbols
for further information

Cleaning & Rinsing

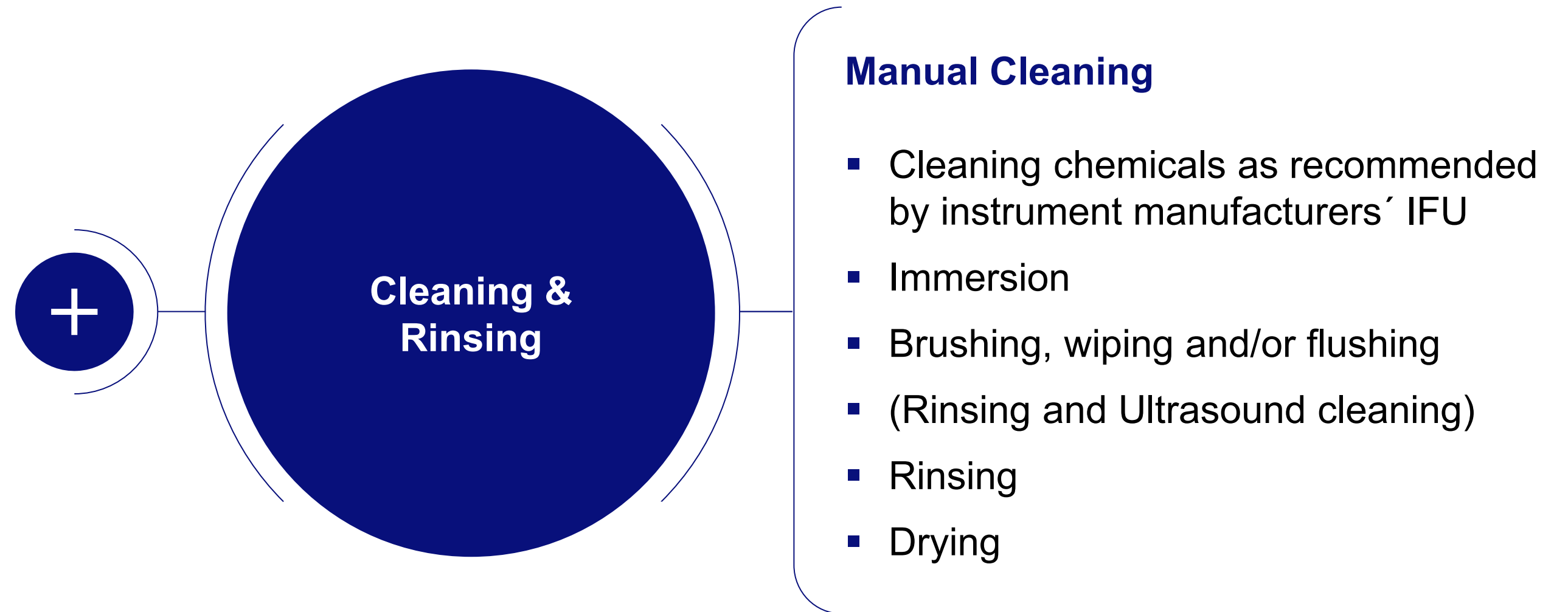
Automated Cleaning

- Preparation for automated cleaning
 - Reduced manual cleaning
- Automated cleaning in washer-disinfector (WD)
- Follow the WD manufacturers advice and the IFU of instrument manufacturer about the cleaning chemicals



Click on the Plus-Symbols for further information

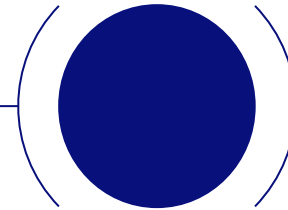
Cleaning & Rinsing



Click on the Plus-Symbols for further information

Automated Cleaning | Reduced Manual Cleaning

- Preparation of detergent solution
 - Follow instructions of process chemical manufacturer in terms of concentration, exposure time and temperature
- Fully immerse the instrument in detergent solution
- Thoroughly wipe or brush all **external** surfaces and flush all **gaps** and **lumens**
- In case of using a cleaning pistol to remove persistent debris in or on a medical device check the maximum/minimum allowed pressure
- Subject the product to ultrasonic cleaning (follow IFU)



Example*:



1. *Immediately after use, thoroughly flush all gaps and lumens of the instrument with enzyme-based detergent using a syringe of at least 10 ml*
2. *Immerse the product in enzyme-based detergent and subject the product to ultrasonic cleaning*
3. *Thoroughly rinse the product with deionized water using a cleaning pistol or other rinse device*
4. *The cleaning pistol or other rinse device must be suitable for cleaning medical devices and deliver a minimum pressure of 1 bar (14.5 psi)*

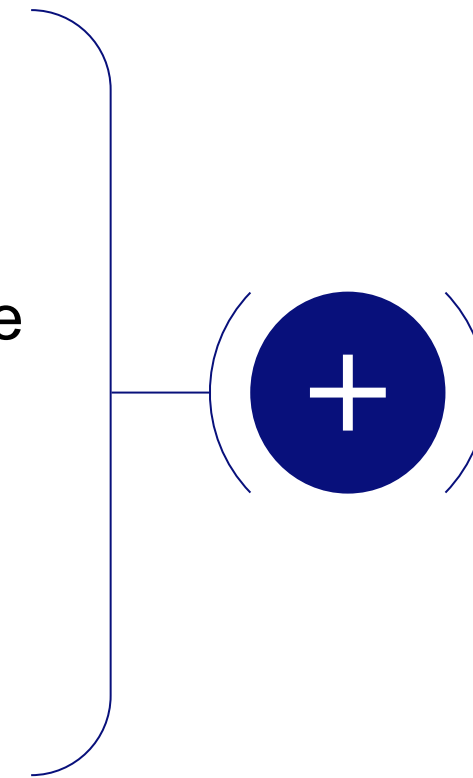
*Source: IFU Olympus TURis/TCRis RESECTOSCOPE

At all times: visibly check the medical device on cleanliness



Manual Cleaning | Brushing

- Preparation of detergent solution
 - Follow instructions of process chemical manufacturer in terms of concentration, exposure time and temperature
- Fully immerse the medical device in detergent solution
- Thoroughly wipe or brush all **external** surfaces



At all times: visibly check the medical device on cleanliness

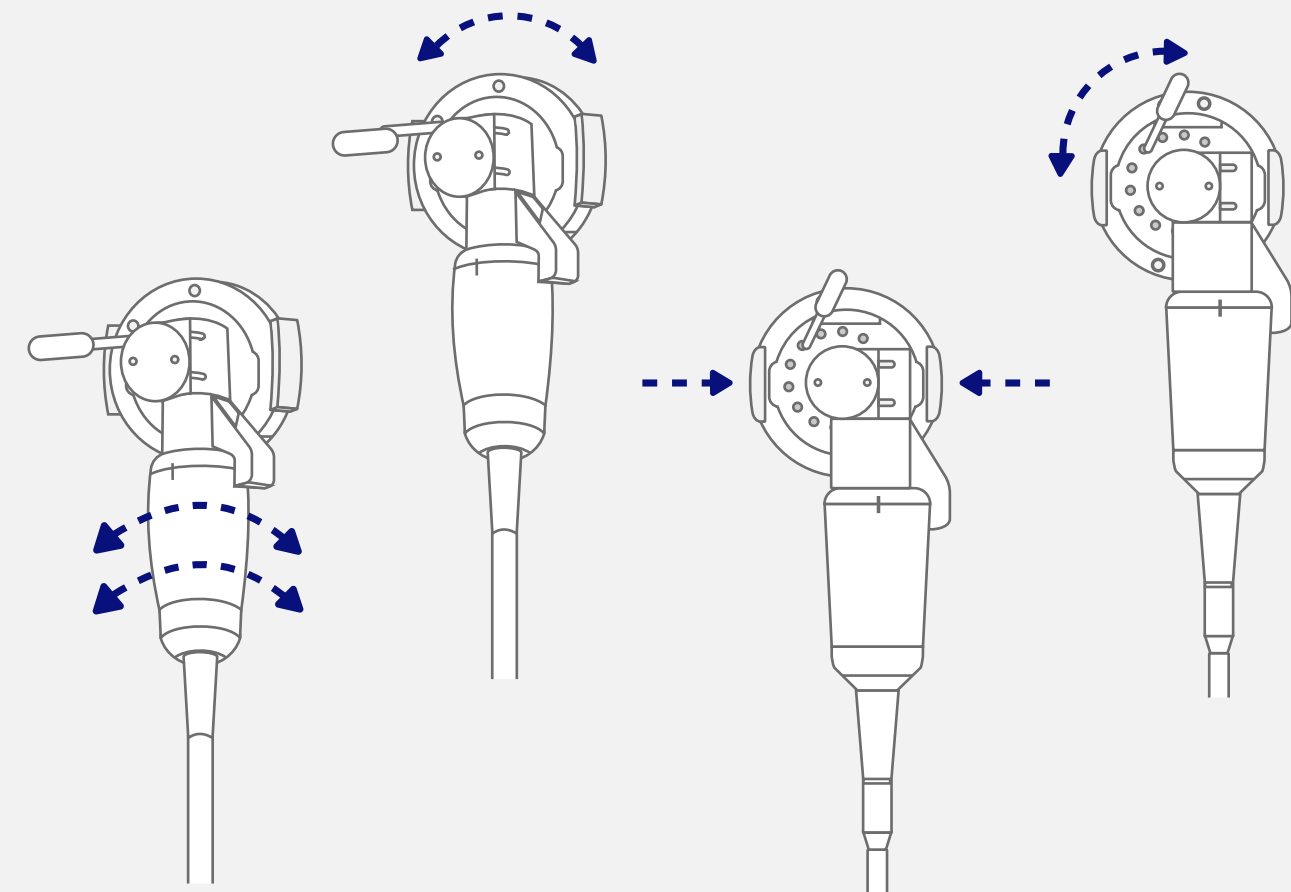


Click on the Plus-Symbol for further information

Manual Cleaning | Brushing

Example*:

1. Fill a clean, large basin with the detergent solution at the temperature and concentration recommended by the detergent manufacturer
2. Immerse the camera head in the detergent solution
3. Confirm that there are no air bubbles on the surfaces of the camera head. If air bubbles adhere to the surfaces, wipe them away using lint-free cloths or the cleaning brush
4. Immerse the camera head in the detergent solution for more than 15 minutes
5. Thoroughly brush or wipe all external surfaces of the camera head using clean lint-free cloths or sponges
6. Move the movable parts of the camera head at least 3 times while immersed in the detergent solution

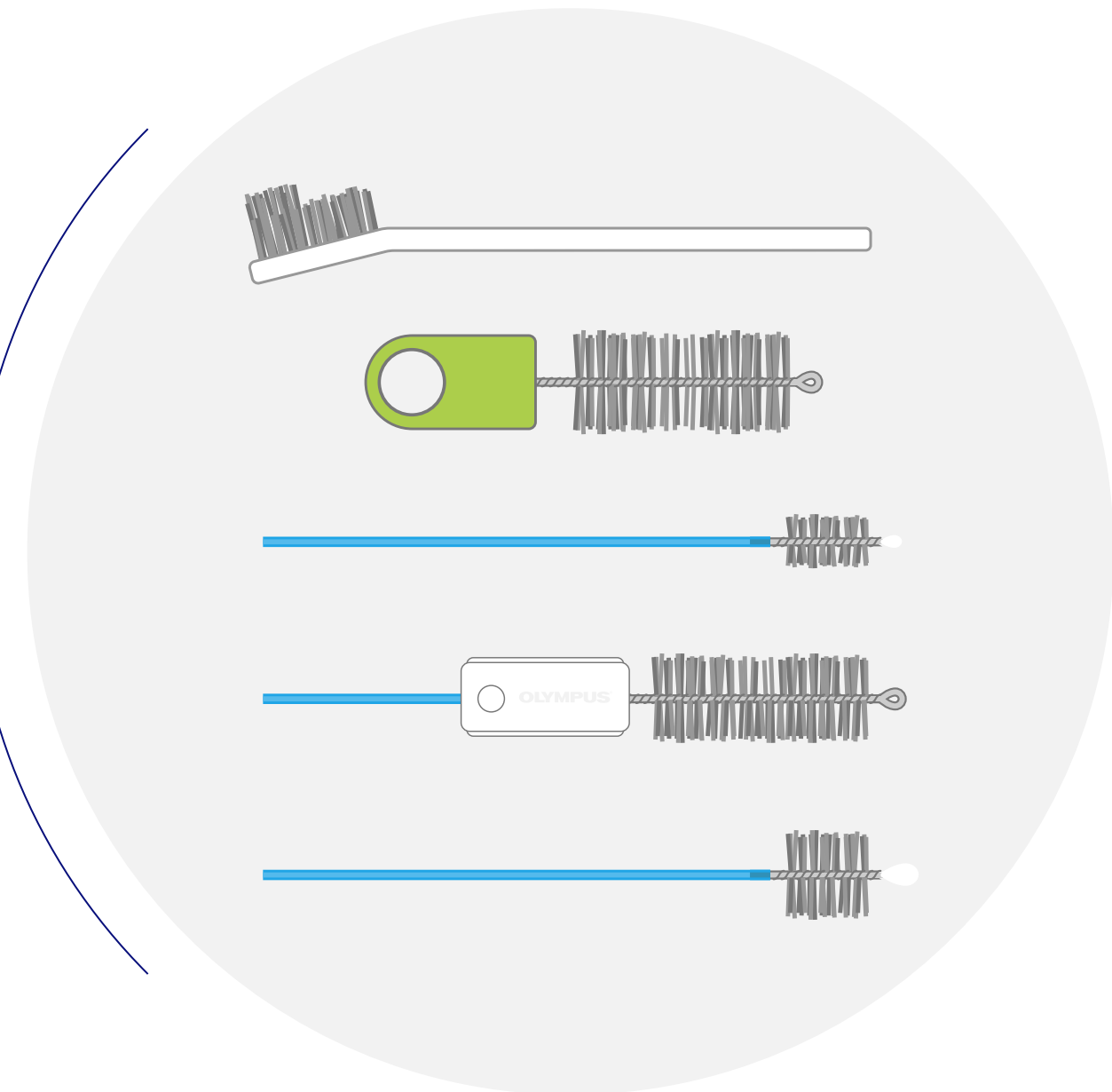


*Source: Olympus IFU CH-S190-08-LB Camera Head

Manual Cleaning | Brushing

- Disposable brush
 - Only used for brushing 1 instrument
 - Forward-backward brushing
- Reusable brush
 - Used for multiple instruments
 - Reprocess after every instrument
 - Carefully check brush prior to use
- Exchange brush if abnormalities are shown
- For defined instruments, special care must be applied when treating the distal end / optics

Example*:



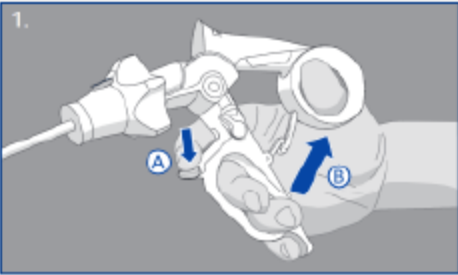
*Source: Olympus

Reprocessing tools | QRGs (Quick Reference Guide)

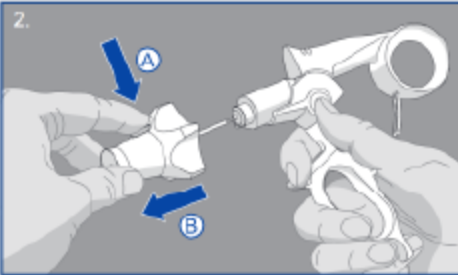
Example*:

OLYMPUS
HICURA
Disassembly, assembly and manual cleaning
Quick Reference Guide

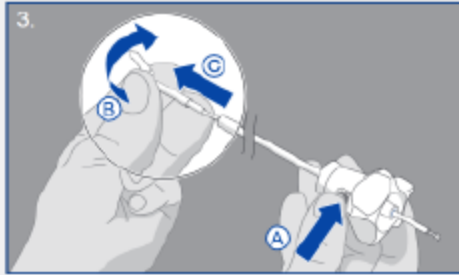
Disassembly

1. 

Unhinge the ratchet and open the handle.

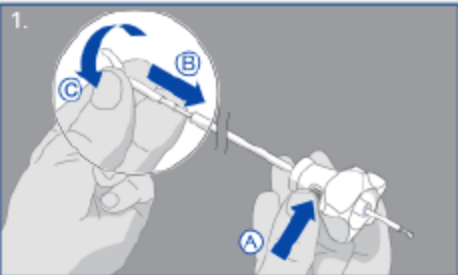
2. 

Press the release button of the shaft and remove the handle.

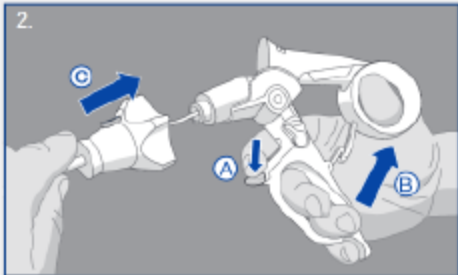
3. 

To avoid injuries, cover the jaws insert with a cloth. Press the release button and turn the jaws insert to remove it.

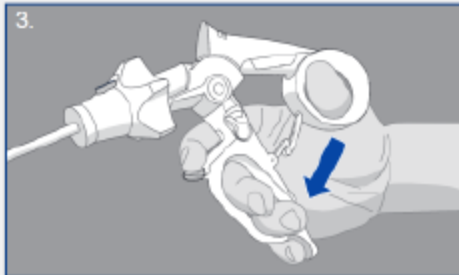
Assembly

1. 

To avoid injuries, cover the jaws insert with a cloth. Press the release button and insert the jaws insert into the shaft. Turn the jaws insert to lock it.

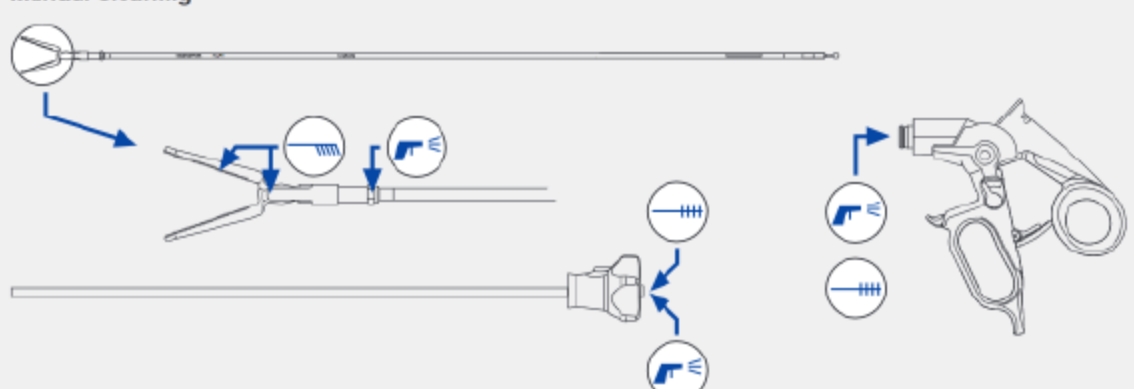
2. 




Unhinge the ratchet and open the handle. Insert the assembled jaws insert and shaft into the handle.

3. 

Close the handle.


Manual cleaning



-  Rinse with detergent
-  Appropriate lumen brush
-  Appropriate surface brush

1. Rinse all parts of the product at least 2 times with alkaline detergent using a syringe of at least 10 ml. The joint of the handle and the joint of the jaw must be rinsed thoroughly. The lumen of the shaft must be flushed from the proximal end.
2. Immerse the product in alkaline detergent for at least 10 min. The jaws must be open.
3. Thoroughly brush all surfaces and gaps at least 10 times with an appropriate surface brush. The joint of the jaw must be brushed at least 20 times. Open and close the jaws while brushing.
4. Thoroughly brush all lumens at least 2 times with an appropriate brush. Press the release button of the shaft while brushing.
5. Thoroughly rinse all parts of the product at least 3 times with fresh alkaline detergent using a syringe of at least 10 ml.
6. Immerse the product in alkaline detergent and subject the product to ultrasonic cleaning for at least 10 min.
7. Thoroughly rinse the product with deionized water using a cleaning pistol or other rinse device. The lumen of the shaft and all gaps must be flushed for at least 60 s. The cleaning pistol or other rinse device must be suitable for cleaning medical devices and deliver a minimum pressure of 1 bar (14.5 psi).
8. Dry the product.

i Sterilize the product after cleaning and disinfection. Otherwise, reprocessing will be insufficient. Make sure that the sterilization process meets the requirements of the applicable international standards, such as ISO 17665 and ISO 14007.



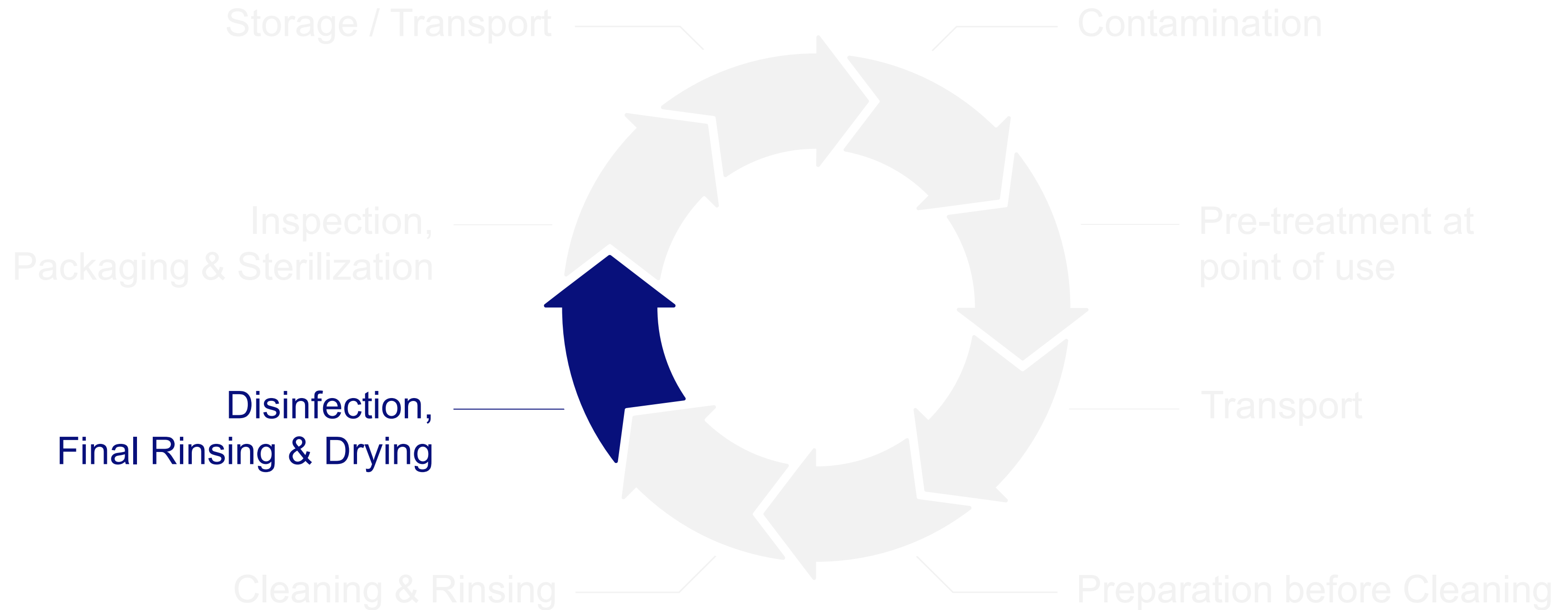
Manufacturer:
Olympus Winter & Ibe GmbH
Kuehnstr. 61
22045 Hamburg, Germany

Refer to the instructions for use for the complete reprocessing instructions.

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*Source: Olympus

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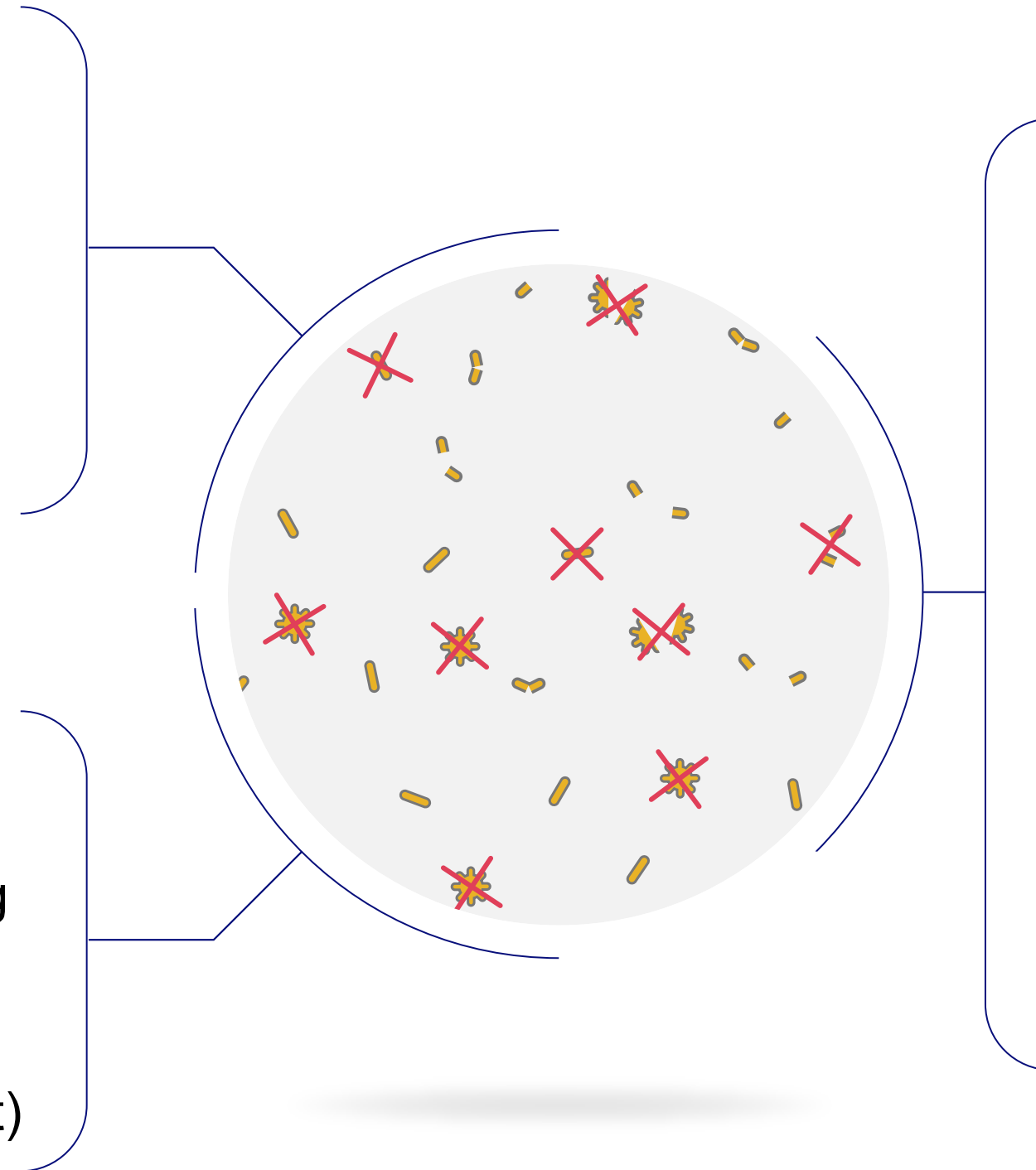
Disinfection

Purpose

- Killing / inactivation of microorganisms except for large numbers of bacterial spores
 - Medical product does not pose a risk of infection

Methods

- **Automated** in a WD according to EN ISO 15883
 - Thermal without chemicals at approx. 90 °C (A_0 concept)

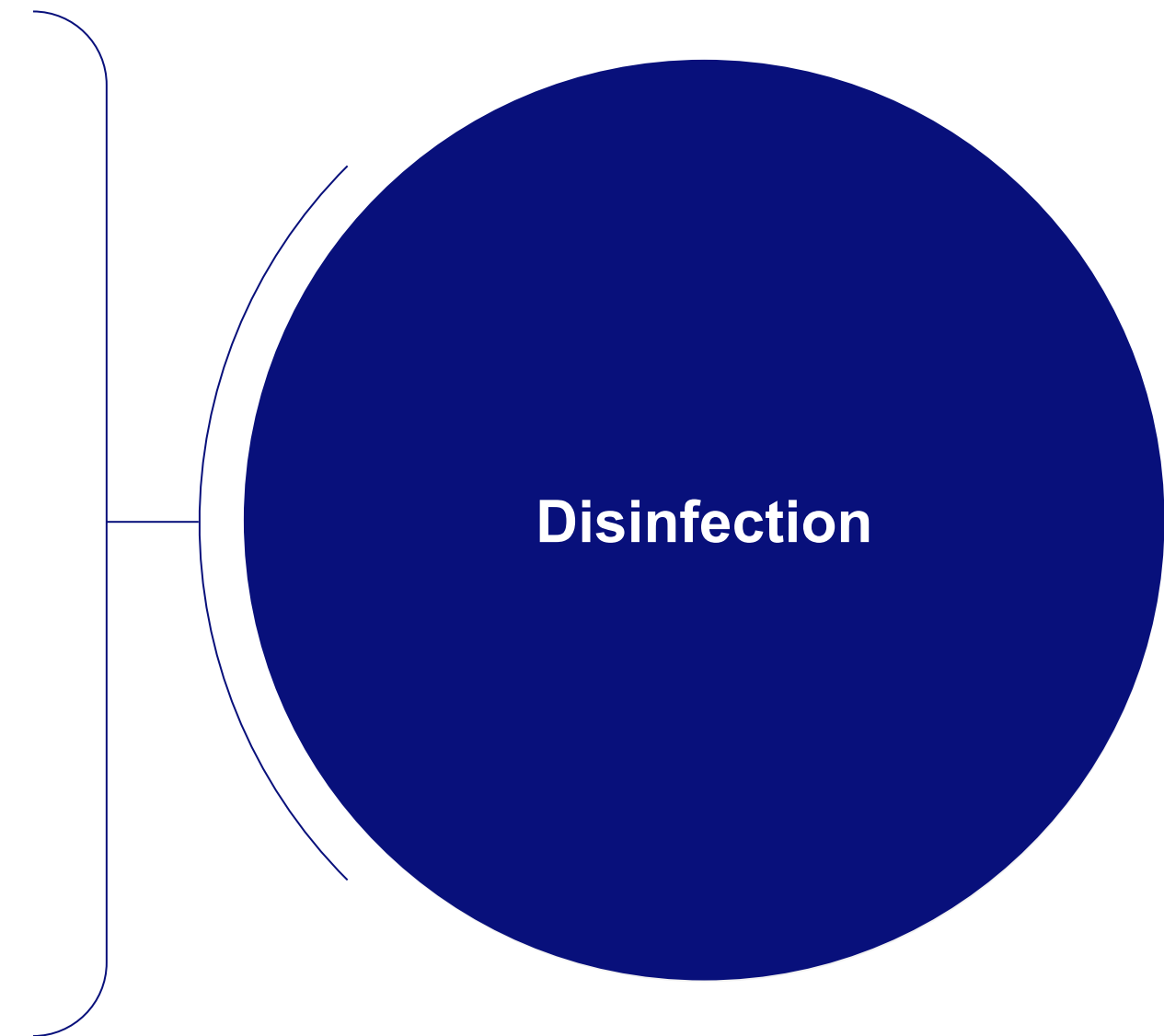


- **Manually** at room temperature with minimum disinfectant activity:
 - Bactericidal (incl. mycobactericidal)
 - Fungicidal
 - Limited virucidal (virucidal & sporicidal in case of terminal disinfection)
- Always follow the chemical manufacturers' instructions in terms of concentration, exposure time & temperature

Disinfection

Automated disinfection of surgical instrument = state-of-the-art!

- No disinfectant needed, as disinfection is done by **hot water!**
- Automated **thermal disinfection** in washer-disinfector (WD) for all heat stable instruments (80°C or higher)
- Check heat stability in IFU of the instruments
- The efficacy of thermal disinfection is defined over the A_0 value
- Rinsing also automated in WD



Automated Disinfection | The A_0 concept

- A_0 value depends on time and temperature
- In some countries, A_0 value needs to have a value of 600 for surgical instruments, other countries ask for A_0 of 3000

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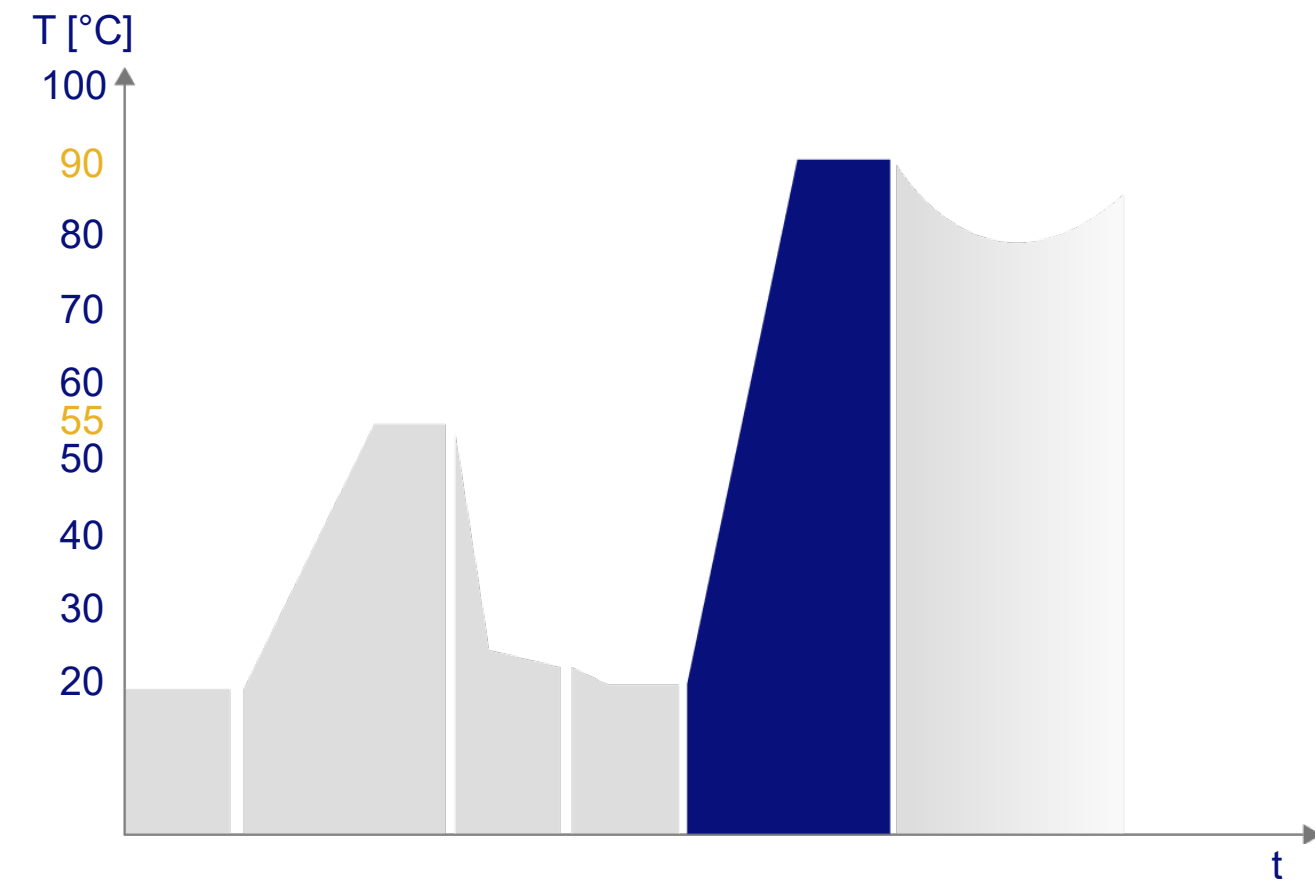
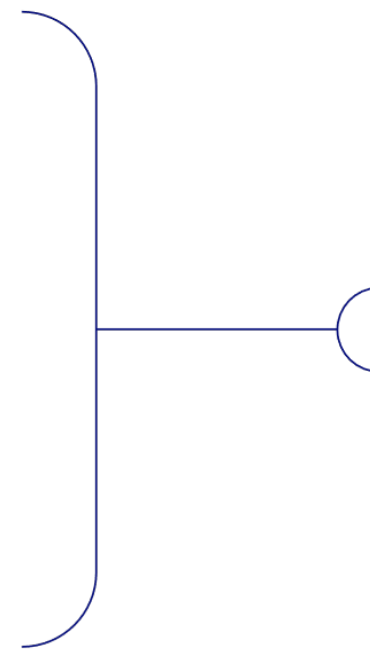


Temp [°C]	Holding time [s]			
	$A_0 = 60$	$A_0 = 300$	$A_0 = 600$	$A_0 = 3000$
95	1.9	9.49	19.0	94.87
94	2.4	11.94	23.9	119.43
93	3.0	15.04	30.1	150.36
92	3.8	18.93	37.9	189.29
91	4.8	23.83	47.7	238.3
90	6.0	30.0	60.0	300.0
89	7.6	37.77	75.5	377.68
88	9.5	47.55	95.1	475.47
87	12.0	59.86	119.7	598.58
86	15.1	75.36	150.7	753.57
85	19.0	94.87	189.7	948.68
84	23.9	119.43	238.9	1194.32
83	30.1	150.36	300.7	1503.56
82	37.9	189.29	378.6	1892.87
81	47.7	238.3	476.6	2382.98
80	60.0	300.0	600.0	3000.0

Disinfection, Final Rinsing and Drying

Thermal Disinfection / Final Rinse

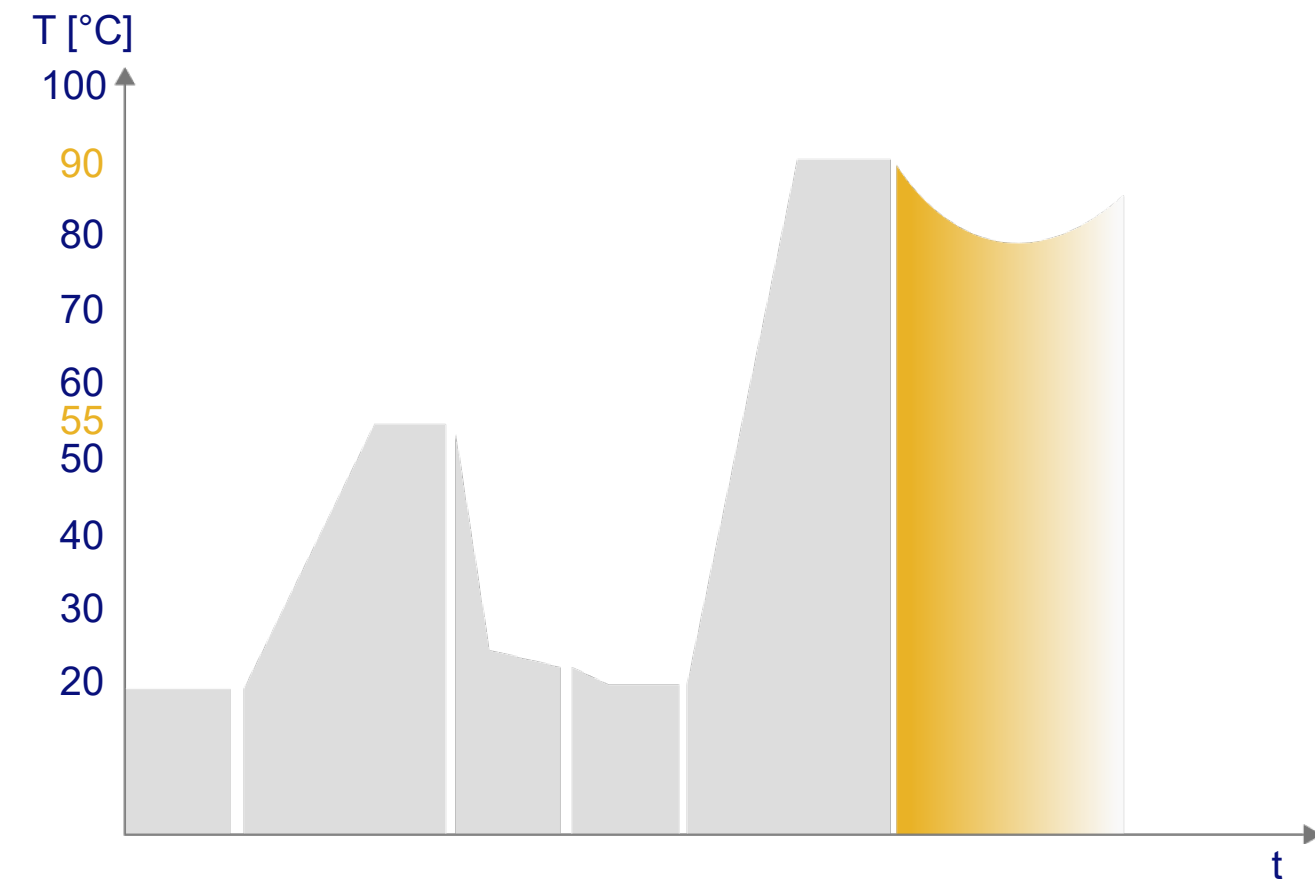
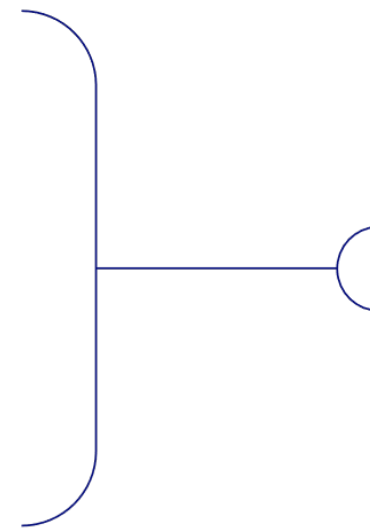
- Fully demineralized water
- Exposure time at 80-93°C as per A_0 concept (minimum range of A_0 of 600 - 3000 as per EN ISO 15883)



Disinfection, Final Rinsing and Drying

Drying

- Sufficient drying must be ensured either through the washer-disinfector or by taking other appropriate measures



Please check possible drying temperature with IFU of each instrument to avoid wrong and too high temperatures

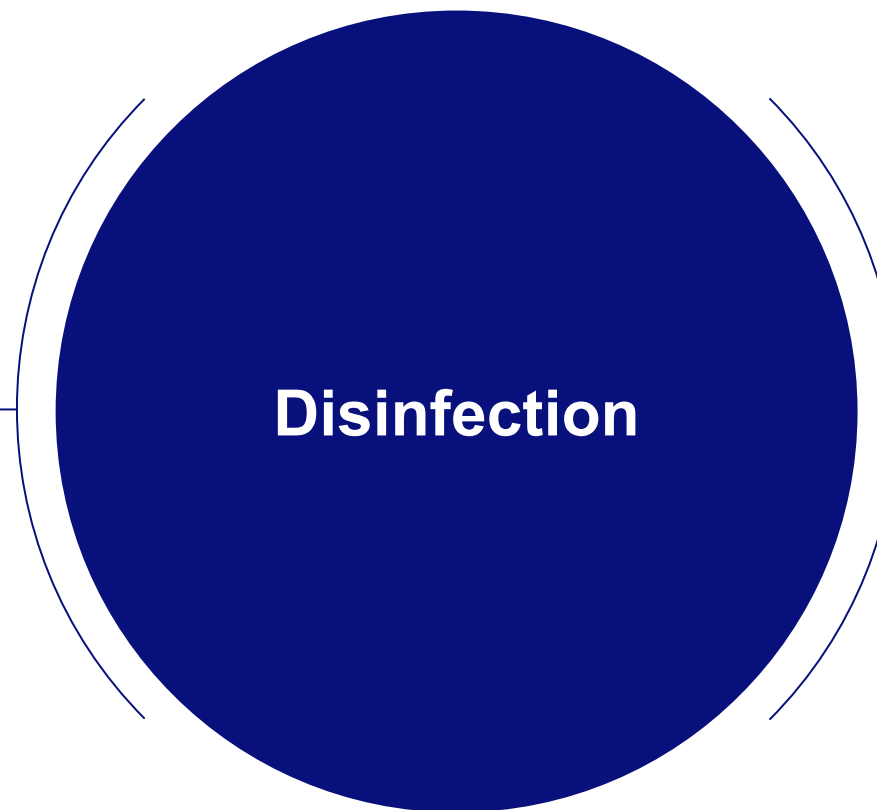


Disinfection

Manual Disinfection

- Possible but not state-of-the-art
- Disinfection not followed by sterilization
 - Use of virucidal and possibly sporicidal disinfectant activity (high level disinfection (HLD))
- Disinfection followed by sterilization
 - Limited virucidal disinfectant activity is enough, e.g. surgical instruments, ureteroscopes etc.

Take care of the ingredients of your chemicals and talk to your chemical distributor



Immersion: take care on contact time and make sure, that all surfaces (inside and outside of the instruments) have contact with disinfection solution

Rinsing

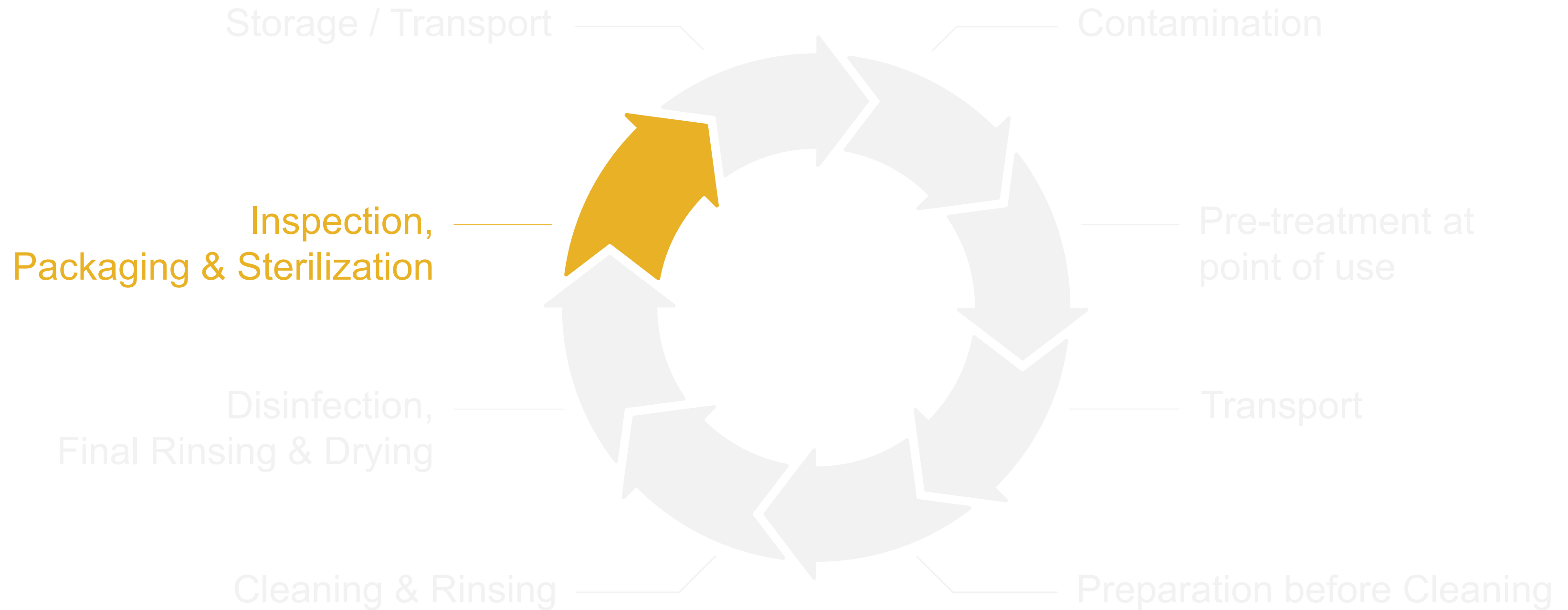
With adequate water quality, depending on following steps:

- Disinfection not followed by sterilization
 - Rinsing to be done with disinfected, soft sterile-filtered or DI (de-ionized) water
- Disinfection followed by sterilization
 - Rinsing to be done with water of drinking water quality



Please refer to the instrument manufacturers' IFU

Reprocessing Cycle for Medical Devices | EN ISO 17664

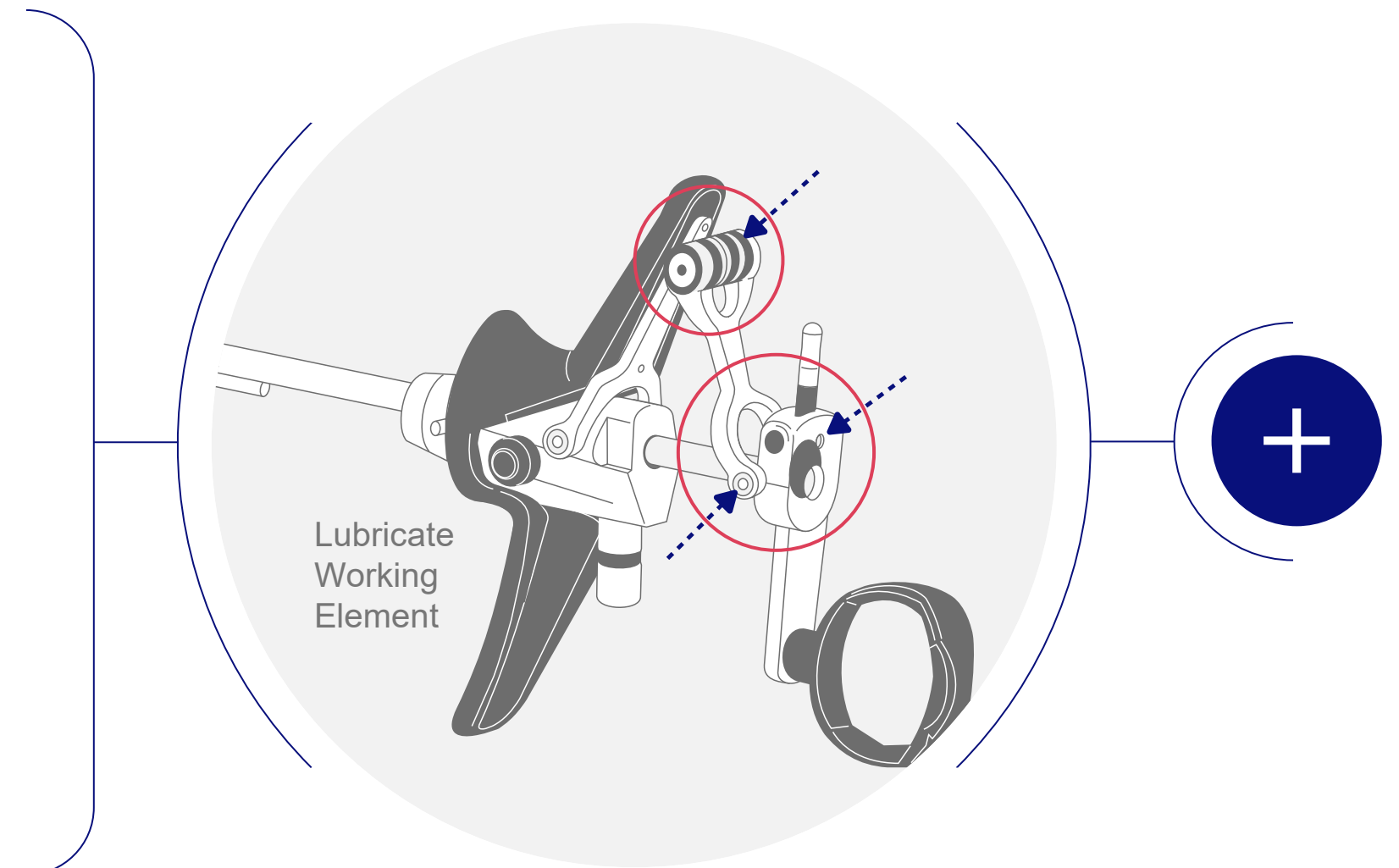


Inspection

After cleaning, disinfection, rinsing & drying

- Visually inspect the product thoroughly
- Use lubricants validated for the sterilization method
- Routine use: Perform inspection / functionality test
- Periodic inspection: Performed by the person in charge of medical equipment maintenance, e.g. the biotechnician

Example*:



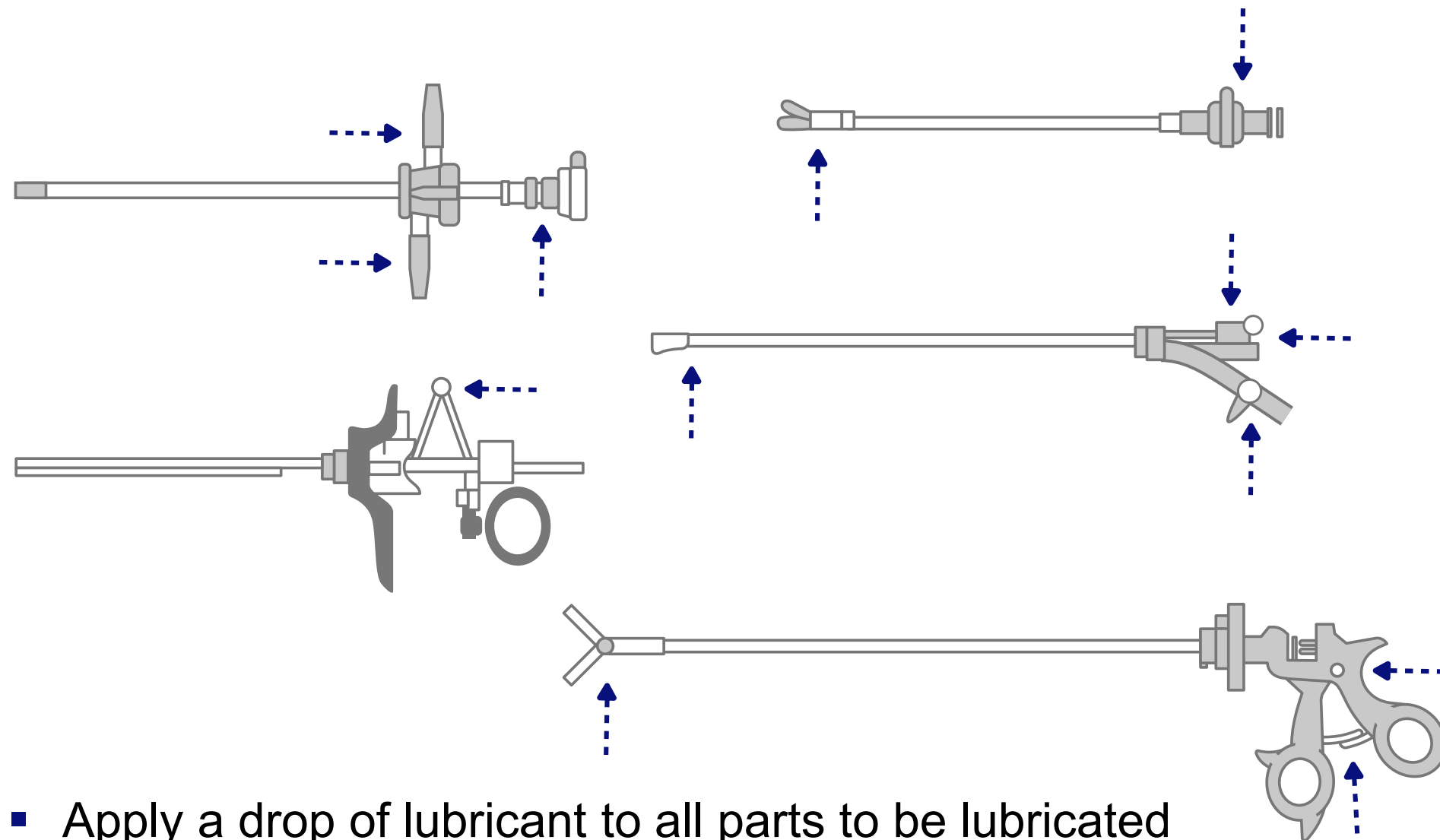
*Source: Olympus

Click on the Plus-Symbol
for further information

Inspection

Moving metal parts

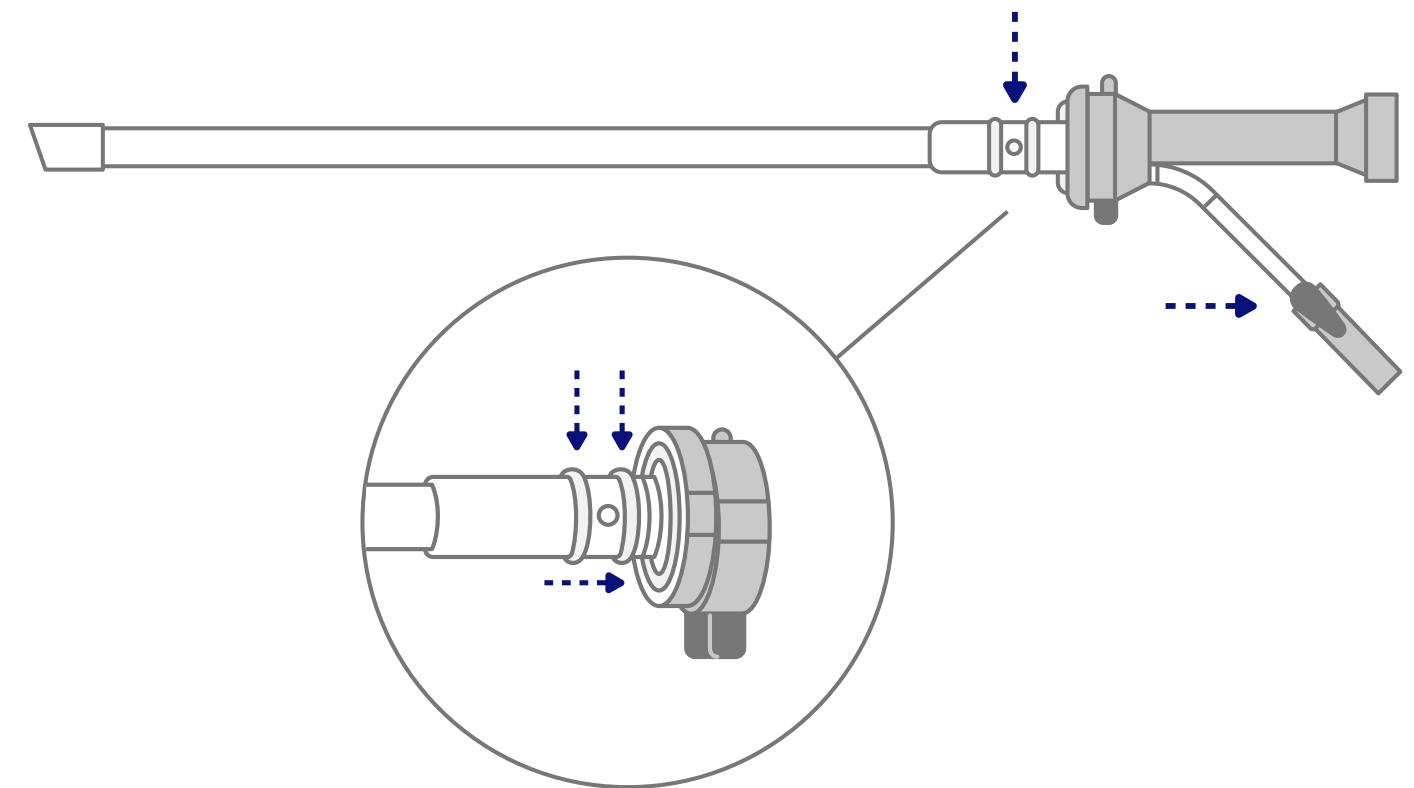
Lubricate moving metal parts in joints or attachment devices



- Apply a drop of lubricant to all parts to be lubricated
- Use a cotton pad to remove excess oil

Silicone sealings

- Apply lubricant to the sealing rings



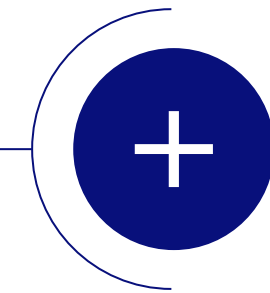
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Inspection

After cleaning, disinfection, rinsing & drying

Attention:

- A number of factors connected with handling and some reprocessing methods may lead to increased wear of the product
- The product must be replaced if signs of wear become visible
- If spare parts are not original parts (e.g. third party products), it might have an impact on durability and function, especially during reprocessing
- In this case, manufacturer cannot take over any responsibility on further results

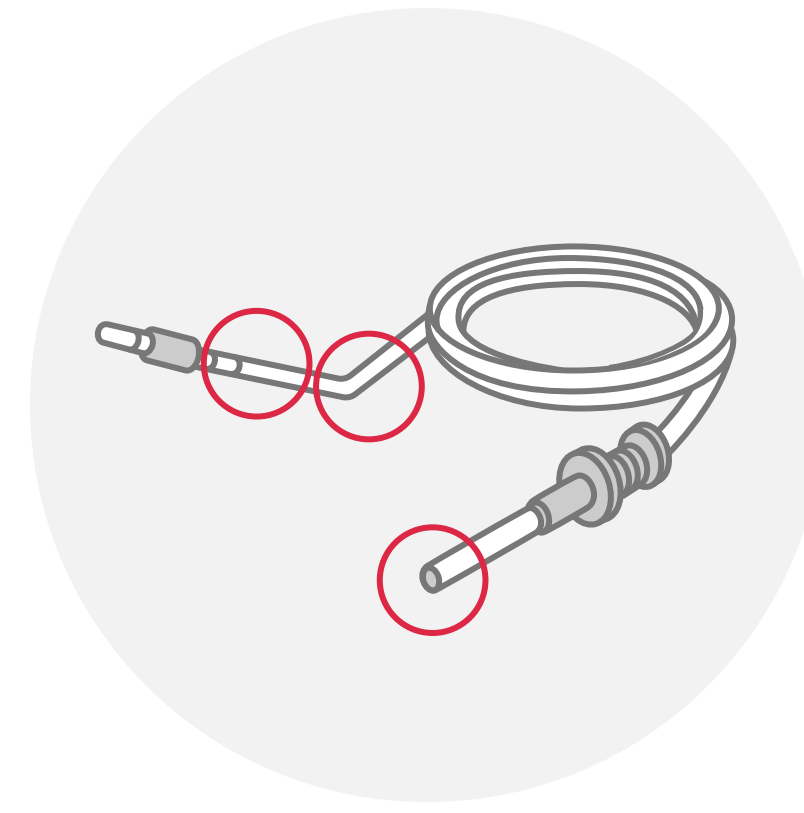


Click on the Plus-Symbol
for further information

Inspection



Unauthorized repair (left) compared to authorized repairs (right)



- Inspect for cuts or other damages to the cable's outer sleeve
- Visually inspect the connector to be plugged into the light source. Make sure, that the cover glass is not damaged

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Packaging | Sterile Barrier Systems (EN ISO 11607-1,2)

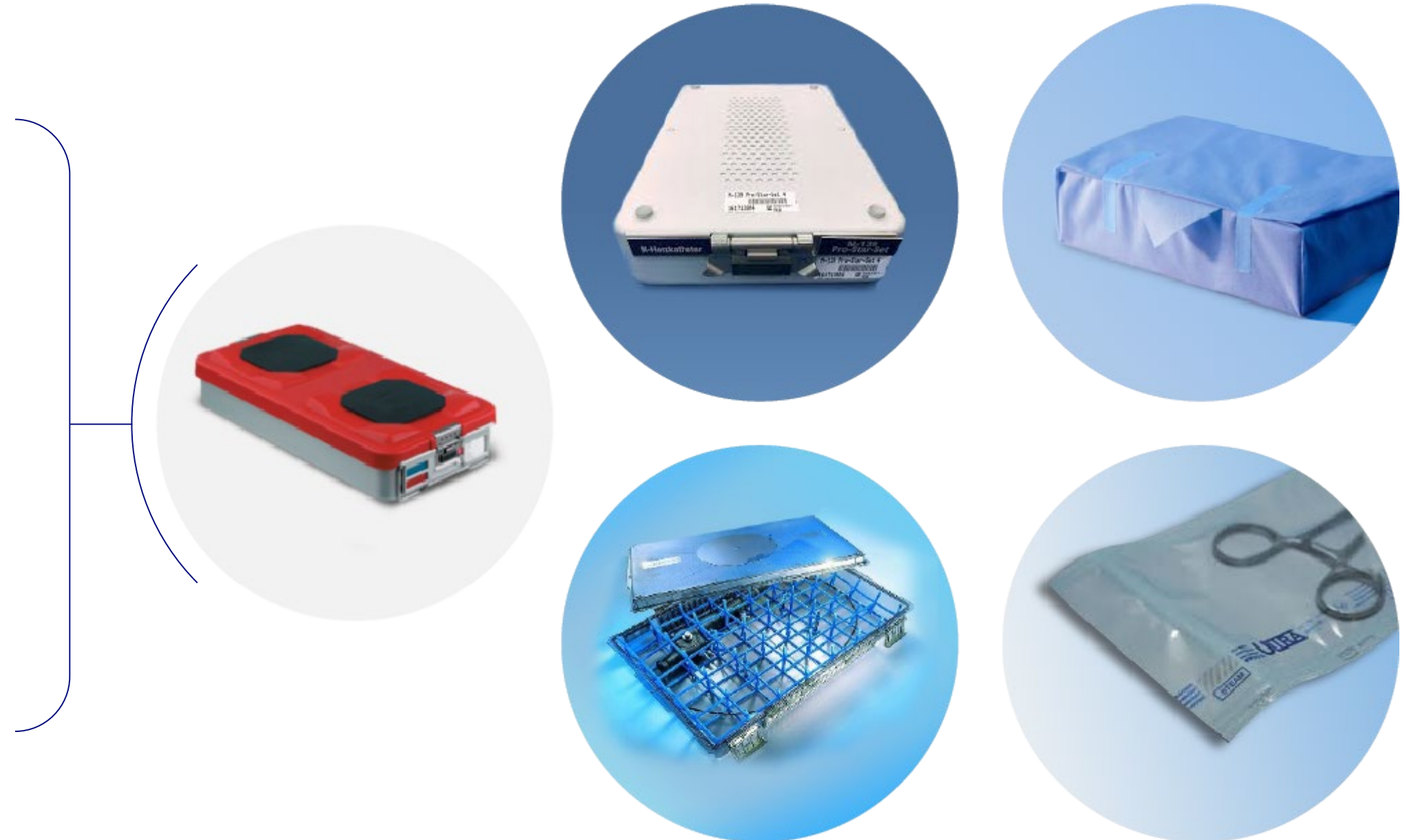
To enable sterilization and to guarantee sterility at adequate storage until reuse

- **Rigid Packaging**

- Container made of chrome / steel, aluminium, plastics

- **Soft Packaging**

- Fleece, foil bags



Packaging | Sterile Barrier Systems (EN ISO 11607-1,2)

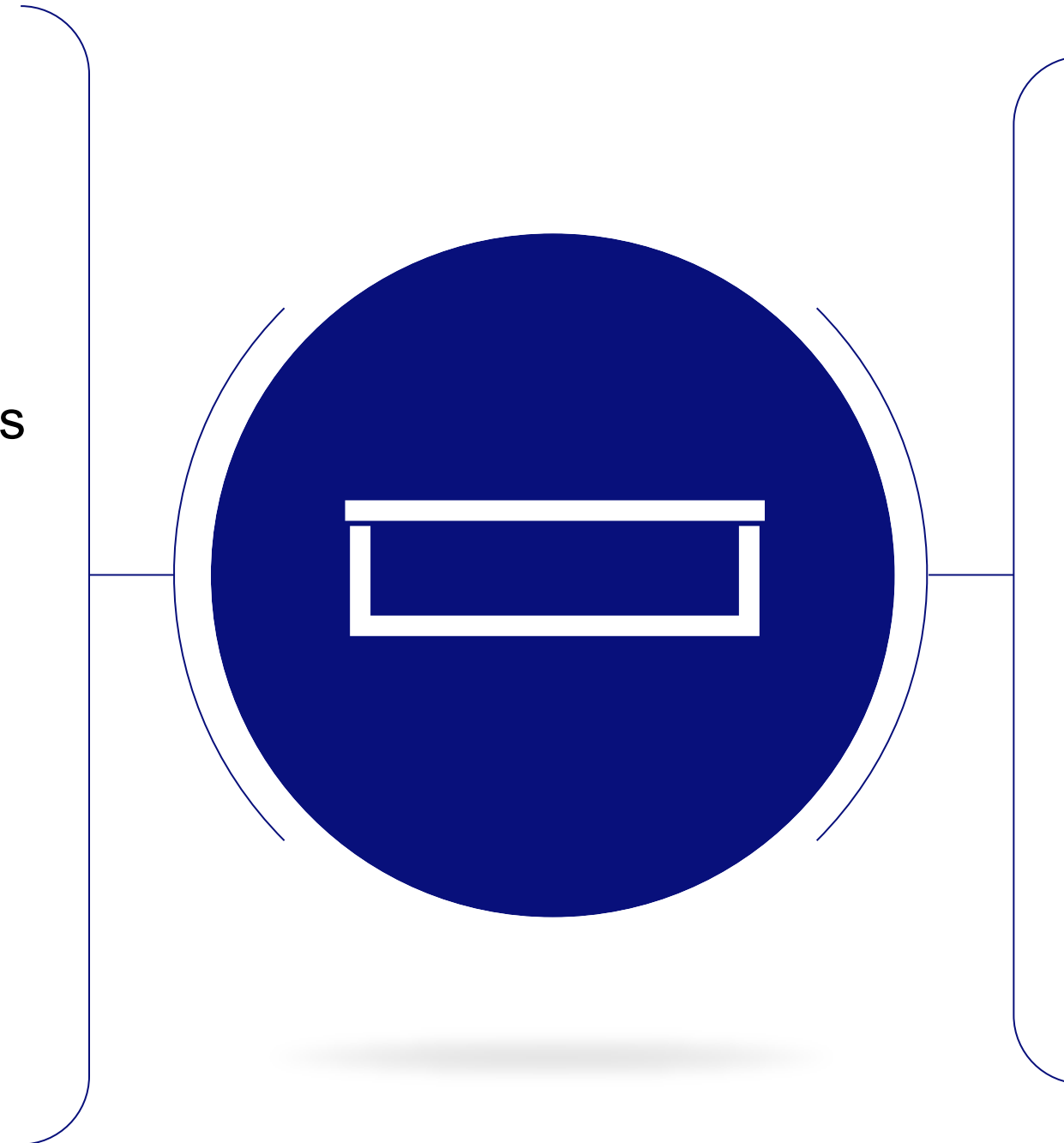
Rigid Packaging

Advantages

- Reusable
- Protection against external influences
- Time saving

Disadvantages

- High purchase price
- High weight
- Fixed sizes
- Follow-up costs (filters etc.)



Soft Packaging

Advantages

- Low weight
- Flexible and adaptable

Disadvantages

- Work- and time consuming
- Running costs
- Risk of perforation
- Weaknesses: stiches and wrinkles

Packaging | Sterile Barrier Systems (EN ISO 11607-1,2)

**After cleaning, disinfection,
rinsing & drying**

Attention

- Not all packaging material is compatible with all sterilization methods!
- Refer to the sterilizer manufacturers' advice for packaging and follow your medical device manufacturers' IFU
- If containers are used as the sterile barrier system
 - Cleaning and disinfection process has to be compatible with containers' material (e.g. high alkaline cleaners and aluminium containers!)

Examples*:

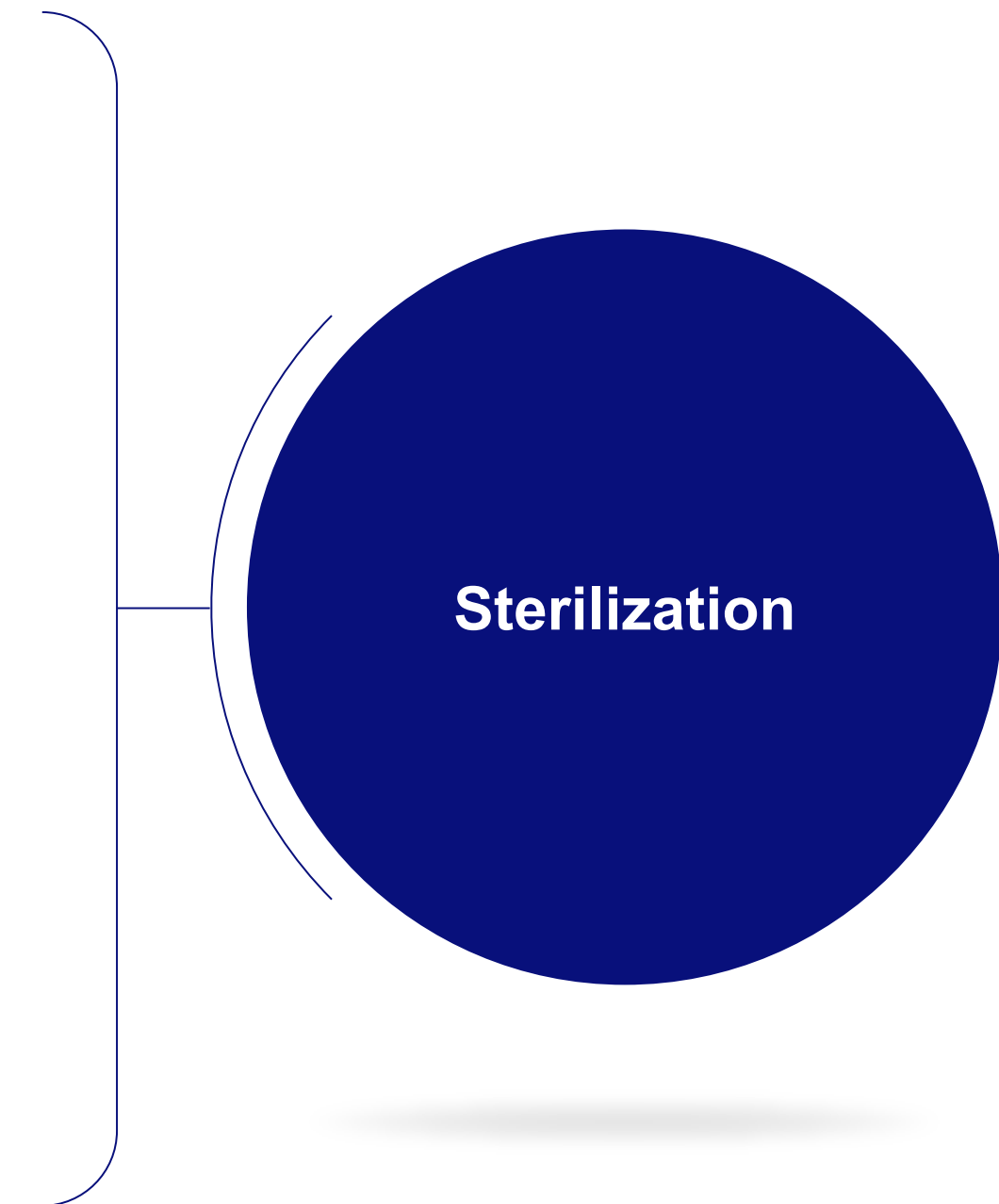


*Source: Olympus

Sterilization

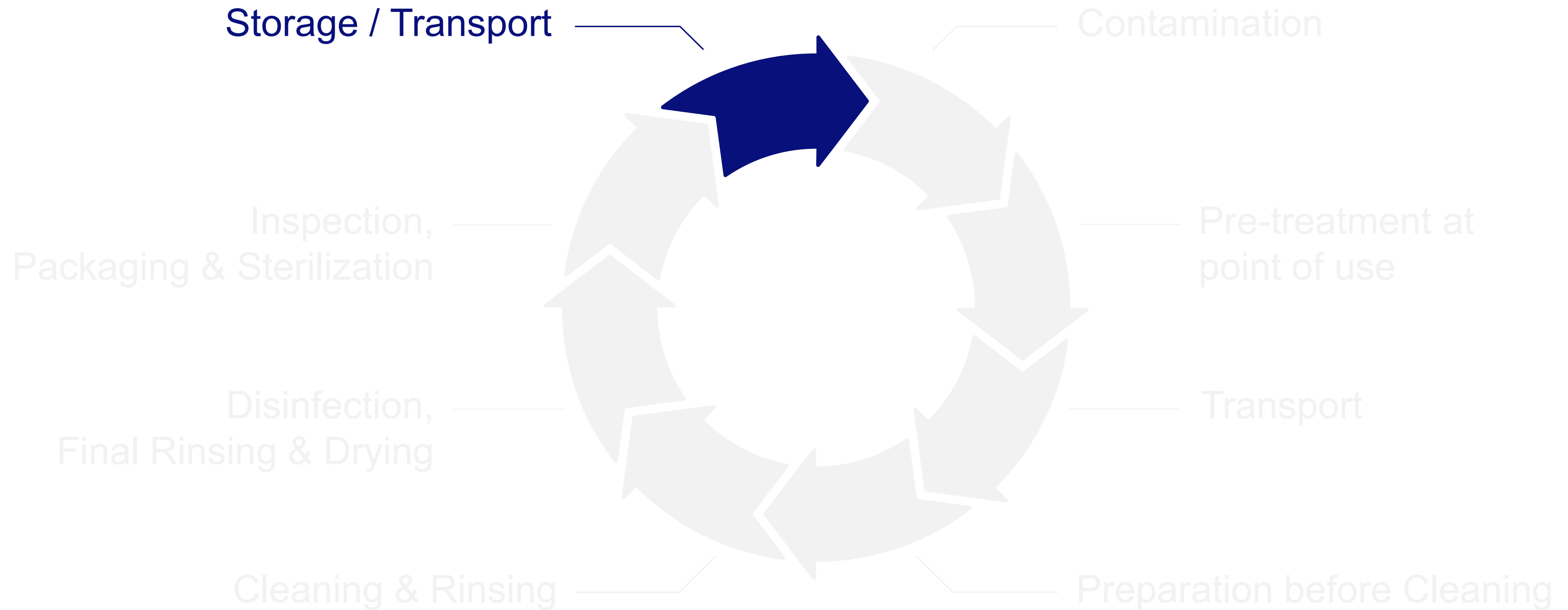
Required for **critical** medical devices (Spaulding classification)

- Use appropriate packaging
- Different sterilization methods available
 - Steam sterilization at 134°C => for most surgical instruments
 - Ethylene oxide at 55°C
 - Low temperature steam formaldehyde (LTSF) at 55°C to 70°C
 - Hydrogen peroxide / H₂O₂ at ~50°C
- Storage like any other medical device in (closed) cabinet



To choose the correct sterilization method follow the respective IFU of each medical device

Reprocessing cycle for Medical Devices | EN ISO 17664



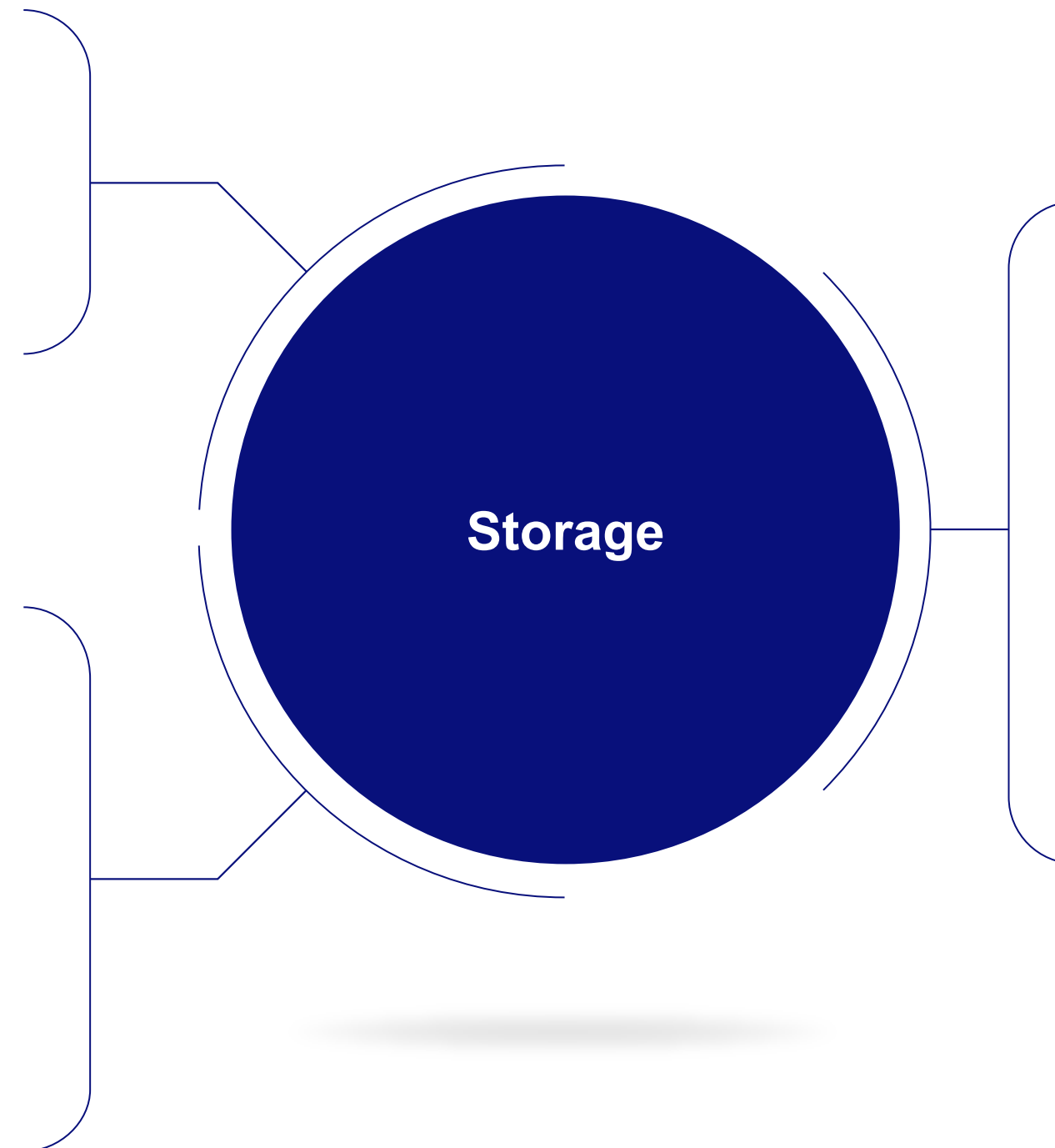
Storage

Purpose

- Avoidance of recontamination and damage

Disinfected items

- Confirm that all surfaces of the reprocessed items are dry
- Store the reprocessed items properly



Sterilized items

- Record the sterile expiration date on the sterile packaging. Do not damage the packaging
- Store the sterilized items in a proper storage cabinet, following your institutional guidelines

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