Netuka's Surgical Clamps

Holder

Clamps

Instructions for Use

OMNIMEDICS

Producer
Omnimedics s.r.o.
Safrankova 1243/3
Prague 5 15500
Czech republic

Contact address:
Omnimedics s.r.o.
Belohorska 2328/277a
Prague 6 16900
Czech republic

Document: IFU-01-03-ENG
Published: 2018-01-16

CE

Contents:

Figures:

Tables:

1 General Information

1.1 Description

Three tools are available for use, which facilitate manipulation with LVAD objects during implantation, replacement or explantation.

A) Netuka's surgical clamps allow fixating the LVAD blood pump when it is manipulated with by the surgeon, including the locking capability.

Figure 1 – Netuka's surgical clamps

B) Holder allows safe fixation of the apical coring knife.

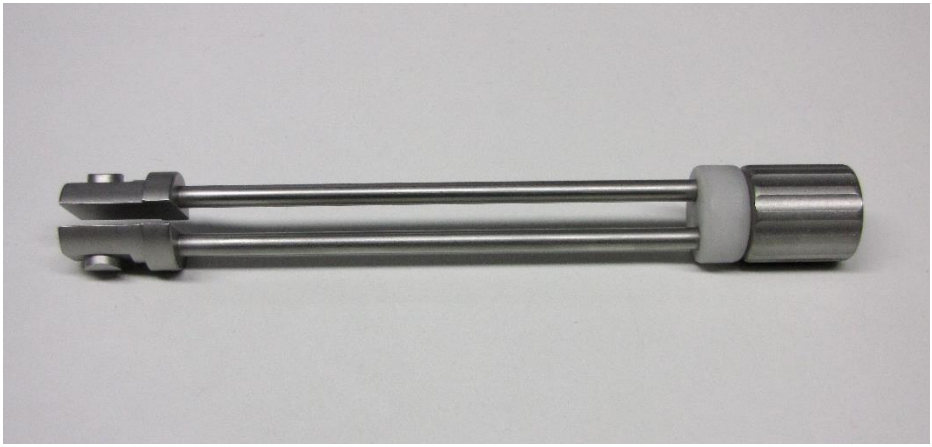


Figure 2 – Holder

C) Clamps facilitate capturing and fixation of the outflow graft

Figure 3 – Clamps

1.2 Warning

- ***All these tools are delivered as non-sterile!!!***
- ***Before use they must always be thoroughly cleaned from dirt, disinfected, checked and sterilised as per the instruction and hospital's rules.***

1.3 Caution

- *Never use extreme force during clamping and fixation of object using these tools.*
- *Inspect each tool for damage before use.*
- *In case of damage, do not use the tool and contact the manufacturer.*

2 Manipulation with Netuka's surgical clamps

Indications:

Netuka's surgical clamps allow fixating the LVAD blood pump when it is manipulated with by the surgeon, including the locking capability.

A – Clamping procedure:

1. Unlock the locking cover on the clamps and verify the smooth motion along the entire motion range.
2. Open the clamps jaws and grab the object to be manipulated. Ensure that the fixation arms do not interfere with any protruding parts of the object.
3. Slide the locking cover of the clamps to the locking position.
4. Clamps are now ready for manipulation with object clamped.

B – Releasing procedure:

1. After finishing manipulating with the object, first release the locking cover of the clamps.
2. Slightly open the clamps jaws making sure that the fixation arms do not interfere with a tissue and any protrusions or distant parts of the object.
3. Carefully remove fixation clams from the operative field.

C – Re-clamping procedure:

1. If the already released object needs to be re-clamped, first check if the locking cover on clamps is unlocked.
2. Carefully open the clamps jaws and grab the object in the operative field making sure that the fixation arms do not interfere with a tissue and any protrusions or distant parts of the object.
3. After grabbing the object in the required position, slide the locking cover on the clamps to the locking position.
4. Clamps are now ready for manipulation with clamped object.
5. After finishing manipulating with the object, the releasing procedure is the same as described in section "***B – Releasing procedure***".

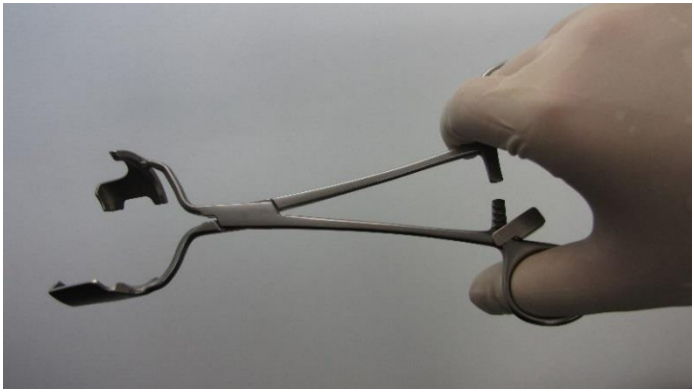


Figure 4 – A1 Unlock the locking cover on the clamps and verify the motion range.

Figure 5 – A2 Open the clamps jaws and firmly grab the object

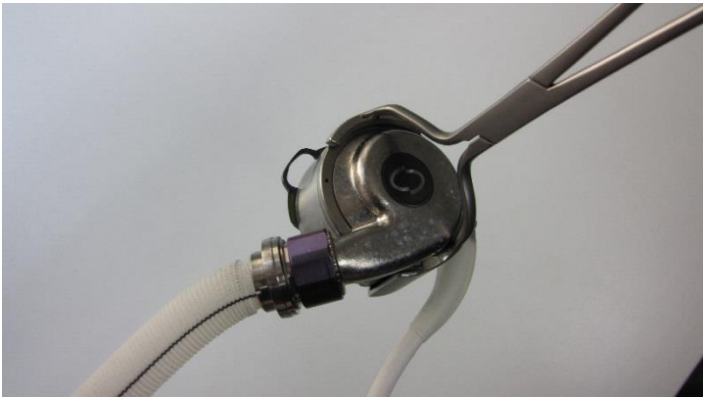


Figure 6 – A2 Object firmly grabbed with no interferences

Figure 09 – A3 Lock the locking cover

Figure 7 – Verification of position

Figure 8 – Verification of position

Figure 10 – B 1 to 3 Releasing the clamps

3 Manipulation with holder

Indications:

The holder allows safe fixation of the apical coring knife.

A – Clamping procedure:

1. Slide the locking ring towards the holder handle.
2. Place the apical coring knife onto the connectors of the apical coring knife holder.
3. Slide the locking ring towards the connectors of the apical coring knife holder.

B – Releasing procedure:

1. After finishing manipulating with the apical coring knife, slide the locking ring back towards the holder handle.
2. Release the apical coring knife from the holder's connectors.

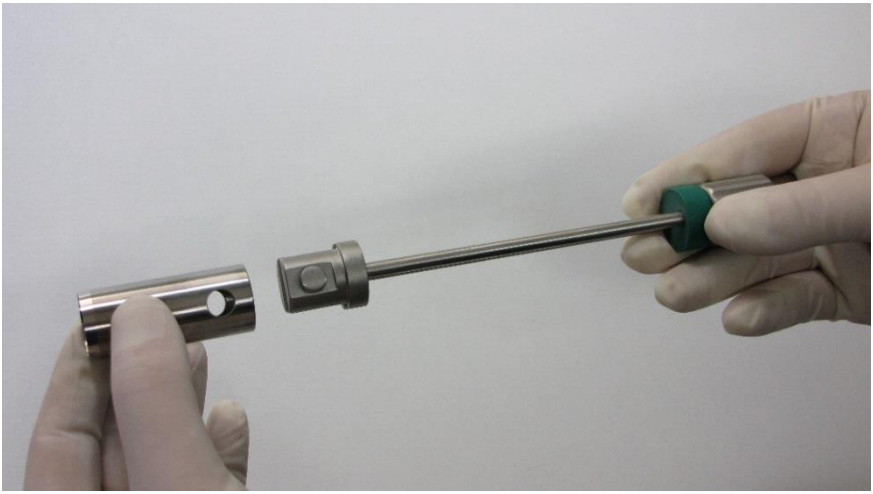


Figure 11 – A1 Slide the locking ring towards the holder handle.

Figure 12 – A2 Put the apical coring knife onto the holder's connector

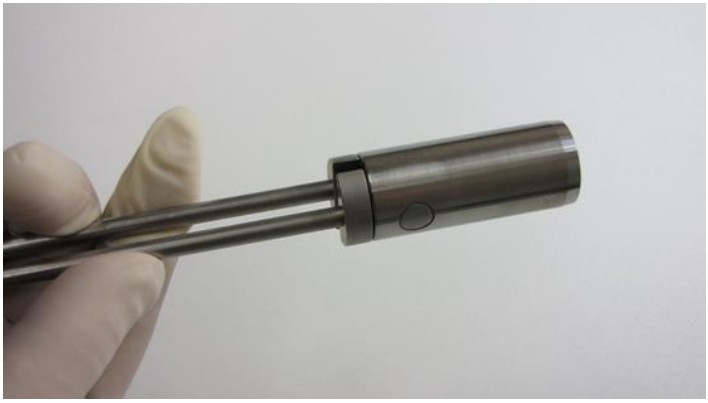


Figure 13 – A2 Verify the correct position of the apical coring knife on the holder's connectors.

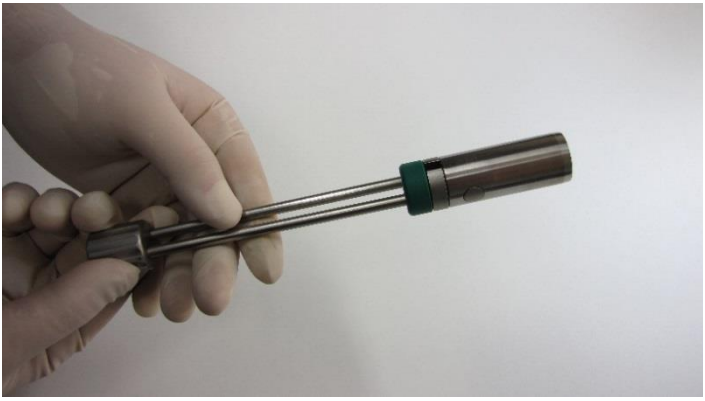


Figure 14 – A3 Secure the holder with the locking ring.

4 Manipulation with clamps

Indications:

Clamps facilitate capturing and fixation of the outflow graft. Clamps shall not be used for tightening the locking socket of the outflow graft.

A – Clamping procedure:

1. Verify the smooth motion along the entire motion range of clamps.
2. Carefully open the clamps jaws and grab the object in the operative field making sure that jaws do not interfere with a tissue and any protrusions or distant parts of the object.

B – Releasing procedure:

1. Slightly open the clamps jaws making sure that jaws do not interfere with a tissue and any protrusions or distant parts of the object.
2. Carefully remove socket clams from the operative field.

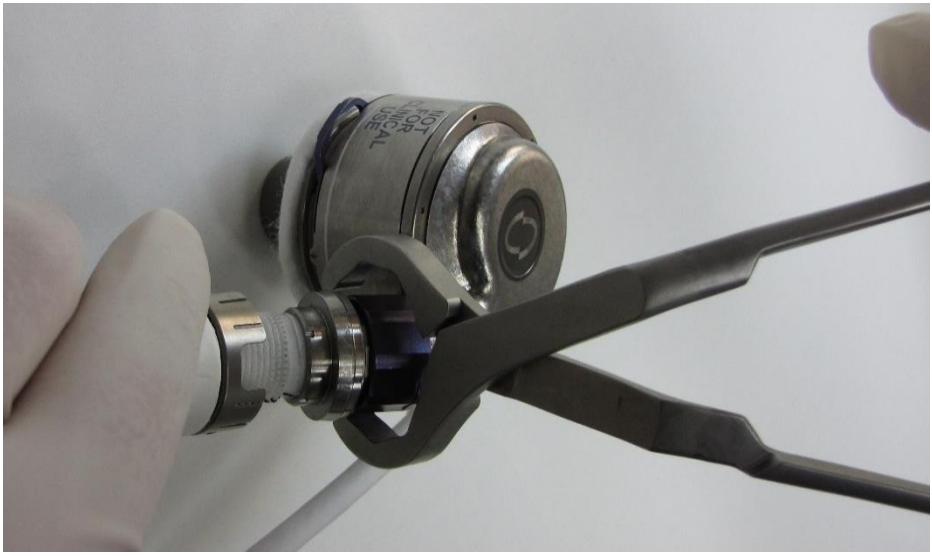


Figure 15 – A2 Opening the jaws and clamping the socket.

Figure 16 – Aligned jaws fully clamped on the socket profile.

Figure 17 - Connecting the protective tube of the outflow graft onto the outflow graft socket.

5. Decontamination and sterilization

This chapter covers instructions for cleaning, disinfection and sterilisation of surgical tools – fixation clamps, socket clamps and the holder.

5.1 Warning

- ***Surgical tools are delivered as non-sterile and must be cleaned and sterilised before using.***
- ***Purpose of this instruction is to ensure a correct level of sterility.***
- ***Do not heat surgical tool to a temperature over 140 °C.***
- ***If you notice any damage or wear that might impair the tool functionality, do not use the tool.***
- ***Inform relevant responsible employees about the damage or wear of the tool.***

5.2 Preparing new tools

Before the first use, the tools must be thoroughly cleaned and then rinsed in distilled water with subsequent lubrication and steam sterilisation (for parameters see "Sterilisation").

5.3 Cleaning

Use distilled water for disinfection, sterilisation and rinsing. Use pH neutral (7) cleaning agent to prevent corrosion. Do not use alkaline, peroxide or acid solutions. Do not use steel brushes for mechanical cleaning.

5.4 Disinfection

The most effective and efficient method for cleaning of surgical tools is the thermal-chemical disinfection (disinfector). Select the program specified by the disinfector manufacturer for disinfection of metal surgical tools.

Chemical disinfection – Select the solution intended for disinfection of metal surgical tools. As a minimum, the solution must have virucidal, bactericidal, tuberculocidal, fungicidal, and mycobactericidal effect. Observe the exposure time recommended by the solution manufacturer.

5.5 Inspection and packaging

Caution:

- *Do not use the tool, if you notice any damage or wear that might impair the tool functionality.*
- *Inform relevant responsible employees about the damage or wear of the tool.*

Inspection:

7. Carefully inspect the tool and ensure that all visible blood and dirt were removed.
8. Carefully inspect the tool visually and check for any damage, wear or other impairment.
9. Verify the functionality of moving parts and check their smooth movement along the entire motion range.
10. Check whether the long and thin parts of the holder are not twisted or bent.
11. After tools cleaning, disinfection and before sterilisation in autoclave, the tools must be lubricated.

Note: Observe the metal surgical tools lubricant authorised manufacturer's instructions. We recommend using the water-soluble lubricant.

Packaging:

- Individual packaging to the polypropylene film (or equivalent).
- Surgical mesh suitable for storing and sterilisation of surgical tools.

5.6 Sterilisation

Nationally applicable sterilisation rules must be adhered to during sterilisation. Correct parameters for sterilisation time, temperature and pressure are indicated in the manufacturer's instructions for the particular sterilisation equipment. Sterilise the tools using a steam (recommended parameters – temperature 132 – 137 °C, duration 4 minutes).

Storage:

- Store the tools after cleaning, disinfection, and sterilisation at a dry place.

6 Deterioration

Rules for achieving the long life of surgical tools:

- *Never use extreme force during clamping and fixation of object using these tools.*
- *For cleaning and disinfection of surgical tools use approved solutions only.*
- *After automated / manual cleaning and disinfection:*
    - *Let the tool completely dry.*
    - *Wrap the tool in approved packing material.*

Limitation of repeated processing:

- The end of life is most often determined according to the wear, damage from use or changed functionality of tools.

Disposal to waste:

- Dispose/recycle damaged or used tools in accordance with all applicable local, national and federal regulations.

7. Symbols

This chapter explains symbols used on components and packaging.

CE	Compliant with EU standards
REF	Catalogue number
LOT	Batch code
SN	Production number
	Production Date
	Manufacturer
	Non-sterile
	Do not use if packaging was damaged
	Read the instructions for use

Table 1 – Symbols used on components and packaging

8. Catalogue numbers

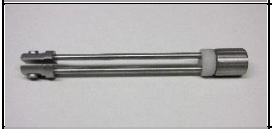
	Catalogue Number	Name
	OCZ-01-01	Netuka's Surgical Clamps
	OCZ-02-01	Holder
	OCZ-03-01	Clamps
	OCZ-04-01	Surgical tools kit

Table 2 – Products catalogue numbers

Contacts for ordering:
E-mail: orders@omnimedics.cz
Phone: +420 232 000 812
Fax: +420 910 103 603

Customer support:
Website: www.omnimedics.cz
E-mail: info@omnimedics.cz
Phone: +420 232 000 813
Fax: +420 910 103 603

OMNIMEDICS

Producer
Omnimedics s.r.o.
Safrankova 1243/3
Prague 5 15500
Czech republic

Contact address:
Omnimedics s.r.o.
Belohorska 2328/277a
Prague 6 16900
Czech republic

Omnimedics has introduced and is using a quality management system ISO 9001:2016 and ISO 13485:2012 for "Development and manufacture of surgical tools, distribution and service of active implantable medical devices and other general medical devices".

Contact information:
Customer support:
Website: www.omnimedics.cz
E-mail: info@omnimedics.cz
Phone: +420 232 000 813
Fax: +420 910 103 603

Contacts for ordering:
E-mail: orders@omnimedics.cz
Phone: +420 232 000 812
Fax: +420 910 103 603

CE

Document: IFU-01-03-ENG
Published: 2018-01-16