EndoCowboy®

REF 15100

LassoTip

REF 15101 to 15103

Manual

English

Version 2.0, issued April 2024

KÖHRER
MEDICAL ENGINEERING

Dear dentist,

thank you for choosing the EndoCowboy® for separated file retrieval. EndoCowboy® is a device that enables the removal of separated instruments from root canals with the lasso technique. For more information, visit our website:

http://endocowboy.com/

Lasso the file …

Contents

1. About this document

These instructions for use apply to the EndoCowboy® (REF 15100) and the LassoTips (REF 15101 to 15103).

If the instructions for use are not followed, Koehrer Medical Engineering GmbH will not be able to offer any warranty or assume any liability for the safe operation and the safe functioning of the devices.

2. Intended user

The EndoCowboy® and the LassoTips are intended for use by licensed dentists only.

3. Warnings and symbols

These symbols are used in the document, or on the packaging or the instrument.


Notes


CE marking


Unique Device Identifier


Medical Device


Manufacturer


Batch code/Lot number


Serial number


Do not re-use/single use only


Non-sterile


Use-by date


Date of manufacture


Consult instructions for use


Sterilizable in a steam sterilizer (autoclave) at 121 °C


Catalogue number

4. Safety

Koehrer Medical Engineering GmbH has designed and constructed the EndoCowboy® and the LassoTips in such a way that when used properly and for the intended purpose it does not pose any danger to people or property.

4.1 Intended purpose

The EndoCowboy® is an endodontic instrument for removing broken root canal file segments from root canals. The separated instrument is removed by placing a wire loop (*LassoTip additionally available*) projecting from a

needle at the end of the EndoCowboy® around the fractured end of the file, after which the loop can be tightened around it, securing it around the file segment to be removed.

4.2 Indications

Endodontic treatments. The EndoCowboy® is an endodontic instrument for removing broken root canal file segments from root canals. The separated instrument is removed by placing a wire loop (LassoTip additionally available) projecting from a needle at the end of the EndoCowboy® around the fractured end of the file, after which the loop can be tightened around it, securing it around the file segment to be removed.

4.3 Contraindications

A clear contraindication for the use of the EndoCowboy®s does not exist. In general, a thorough assessment of the tooth's preservability or worthiness of preservation must be performed. The chances of file removal are to be individually assessed and evaluated on a case-by-case basis. Very deeply apical located files are particularly difficult to remove, especially in curved root canals, and carry the risk of perforation when creating the access cavity. This requires a high level of experience and skill from the operator. However, the risk of perforation is not due to the instrument itself, but to the fundamental treatment technique used during file removal. In non-infected cases, if the instrument does not extend beyond the apical foramen, leaving the instrument in place may be considered if the operator considers the risk of perforation to be greater than the risk of complications due to the fractured instrument. In infected root canals, revision treatment and thus also file removal are generally considered an attempt at preservation to avoid definitive extraction of the tooth.

4.4 Intended use

Removal of fragments (fractured endodontic instruments) from root canals. Before using the EndoCowboy®s, i.e., removing a fractured instrument, access to the instrument to be removed must be created using endodontic files. Furthermore, exposure of the instrument head must be achieved, preferably using ultrasound or sonic instruments, to be able to grasp the instrument with the lasso.

4.5 Improper use

Any other use is prohibited and may pose a risk. The manufacturer cannot be held liable for any damage resulting from incorrect usage. The operator will be held liable and bears all risks.

4.6 General safety instructions

- Before use, check that the instrument has not been damaged and that all components are present and correctly installed (see also Assembly EndoCowboy® and LassoTip).
- Do not modify the EndoCowboy® or the LassoTips.
- Provide the user manual to the user (see intended user).
- Cleaning and maintenance may only be carried out by individuals who have received training in the handling materials or parts contaminated by infectious diseases.
- Wear gloves when using the EndoCowboy® and the LassoTips.
- Use a rubber dam when treating the patient.

5. Safety and Liability

It is the responsibility of the user to check the products prior to use to ensure that they are suited for the intended purpose. In case of contributory negligence by the user, Koehrer Medical Engineering GmbH partially or totally declines liability for all resulting mages, particularly if these are due to non-observance of our recommendations for use or warning as well as inadvertent misuse by the user.

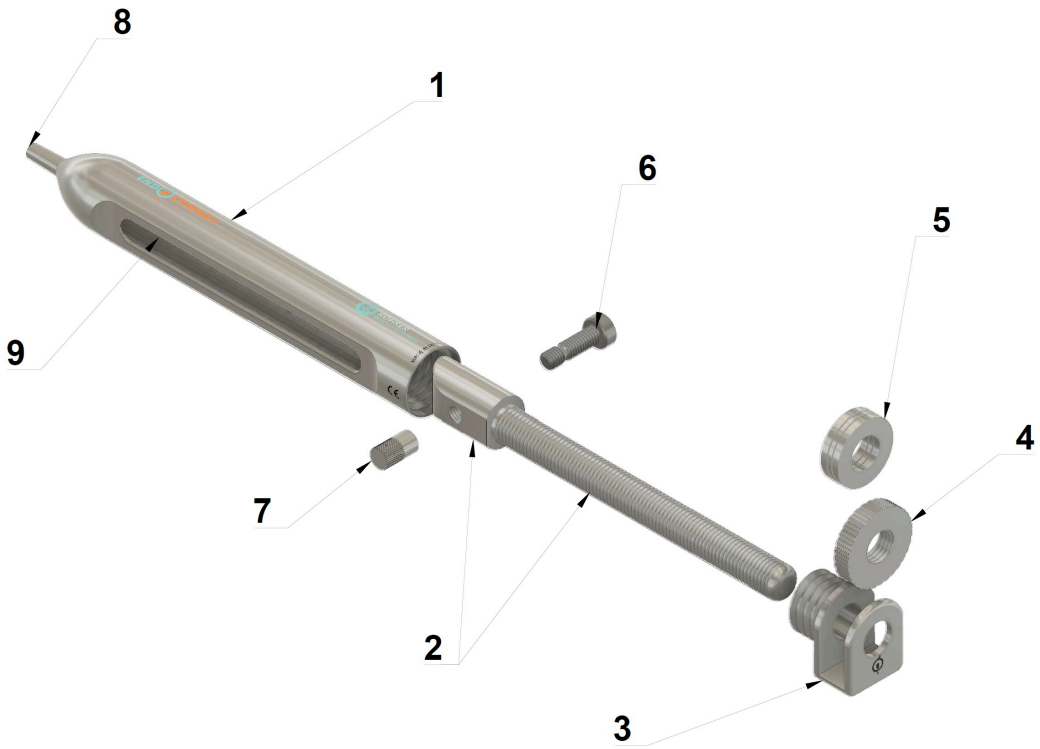
Store products out of children’s reach.

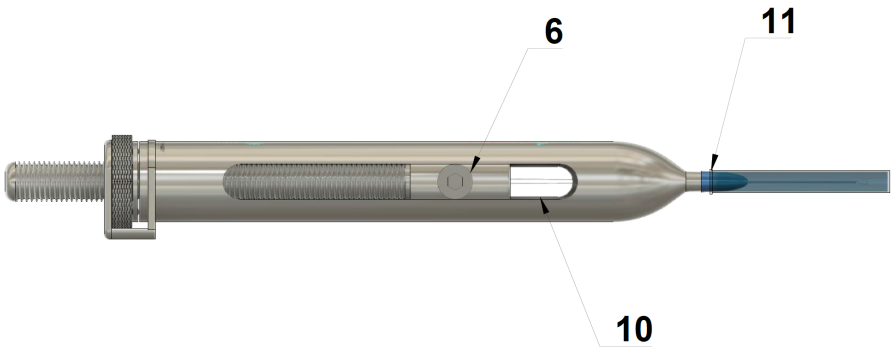
For dental use only.

The operator is required to report any serious incident that occurs in connection with the device to the manufacturer Koehrer Medical Engineering GmbH and to the competent authority of the Member State in which the operator is established.

6. Construction of the EndoCowboy® and LassoTip

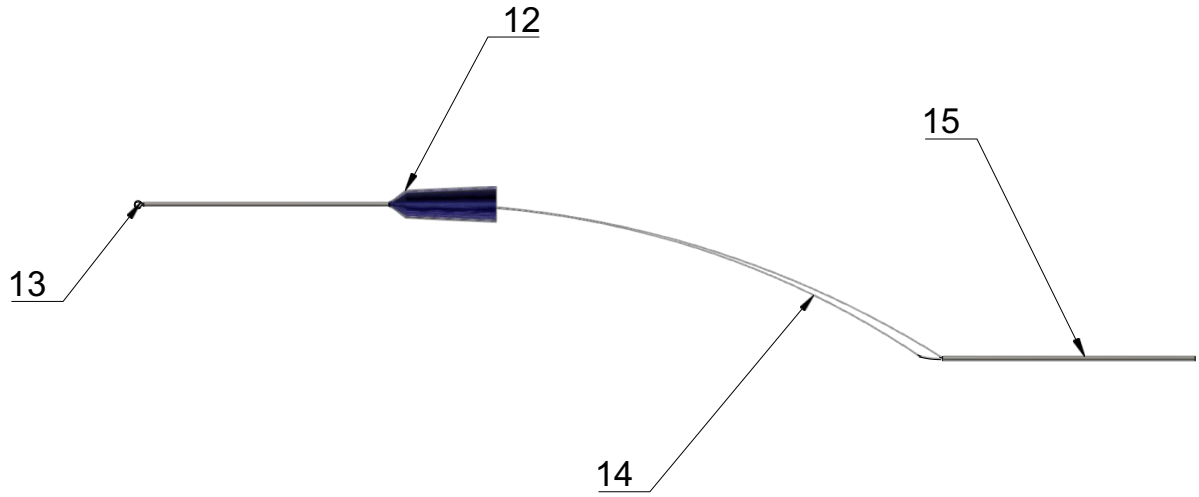
EndoCowboy®





1. Body housing
2. Threaded rod with slide
3. Adjusting wheel abutment
4. Adjusting wheel
5. Axial ball bearing
6. Guidance screw
7. Fixing nut
8. Coupling for LassoTip
9. Side access window with recess
10. Lateral guide rail
11. LassoTip

LassoTip



12. Needle
13. Lasso
14. Wire
15. Lasso-insertion aid

7. Assembly and disassembly of the EndoCowboy®

Caution: When unscrewing, all parts of the adjustment wheel mechanism come loose. The disassembly should be done on a secure surface to avoid damage to the components.

The EndoCowboy® can be completely disassembled if necessary. To disassemble the EndoCowboy®, the fixing nut (7) must first be unscrewed. The enclosed hex key can be used to remove the guidance screw (6). Then remove the adjusting wheel abutment (3) by unscrewing. After this, the threaded rod with slide (2) can be pulled out of the body housing (1). By unscrewing the threaded rod (2) from the adjustment wheel abutment (3) the adjusting wheel (4) and the axial ball bearing (5) are released.

When mounting, make sure that the guidance screw (6) is screwed in, on the side of the lateral guide rail (10). So that the guidance screw (6) lies in the lateral guide rail (10). This ensures that the fastening mechanism for the wire is easily accessible via the side access window with recess (9). Insert the axial ball bearing (5) into the recess of the adjusting wheel (4).

8. Assembly of the LassoTip onto the EndoCowboy®

Videos for installation at: www.endocowboy.com/the-technique

The LassoTip must be mounted before treatment.

1.

1. For this purpose, it is recommended to move the threaded rod (2) with the adjusting wheel (4) to the middle position (middle of the side access window with recess (9)) to allow sufficient space for threading the insertion aid (15).

2a.

2. The insertion aid (15) is guided through the bore of the coupling (8) and received on the side of the access window with recess (9). This works best when the EndoCowboy® is held down with the side access window with recess (9). The threaded rod with slide (2) thus automatically guides the insertion aid (15) to the side access window with recess (9).

2b.

3.

3. The wire (14) is then carefully pulled through and the needle hub (12) is pushed with some pressure on the coupling.
Caution: The wire (14) should not be pulled too hard so that the lasso (13) does not close before use.

4.

4. The fixing nut (7) should only be loosened by about half a turn.

5. With light pull on the insertion aid (15), the wire (14) is to be threaded through the gap between the locking nut (7) and slide (2) and then to be winded about 90 ° around the lead screw (6).

6. Tighten the locking nut (7). The lasso-insertion aid (15) can be cut with a scissor or to be left uncut.

7. Now the wire (14) can be tightened by turning the adjusting wheel (4) in a clockwise direction.

9. Setup of the EndoCowboy®

Setup videos at: www.endocowboy.com/the-technique

8. The needle (12) of the LassoTip can be pre-bent as required to provide better access to the cavity of the tooth to be treated.

9. For the safe placement of the lasso (13) around the separated instrument, a bend of the lasso (13) by about 45° is recommended. This works best with the tip of a DG 16 endo explorer.

10. Usage of the EndoCowboy®

Videos for use at: www.endocowboy.com/the-technique

Prior to application of the EndoCowboy®, an access cavity to the separated instrument must be created, approximately ISO 70 (0.7 mm). The size of the access depends on the size and location of the separated instrument. After this, the head of the instrument should be exposed at least 1 mm with an ultrasonic or sonic preparation so that the lasso (13) can be placed around the fractured instrument.

Now the EndoCowboy® can be used. The EndoCowboy® should be held like a handpiece. The thumb comes to rest in the front area of the side access window with recess (9). After placing the lasso (13) around the separated instrument, the lasso must be closed by tensioning the wire (14). One of the unique characteristics of EndoCowboy® function is that the dental assistant, by turning the adjusting wheel (4) clockwise, is in charge of tensioning the lasso. This allows the doctor to fully concentrate on placing the lasso around the separated instrument. Due to the built-in ball bearing (5), the tension of the wire (14) can be adjusted very precisely with the adjusting wheel (4). In order to be able to exert enough tension on the separated instrument, the lasso (13) must be pulled tightly around the instrument. Too much tension of the lasso (13), however, must be avoided, since otherwise it can lead to tearing of the wire (14). We recommend practicing the procedure with the assistant before the first application on an extracted tooth or plastic block.

11. Hygiene and maintenance of the EndoCowboy®

The EndoCowboy® is completely made of stainless steel and if undamaged and handled with care, the EndoCowboy® can be reused multiple times. The user is solely responsible for determining whether the product can be used repeatedly and how often it should be used, based on the particular application and any wear and tear on the product. If components show any damage, they must be replaced. In case of doubt, components should always be sorted out and replaced early.

The EndoCowboy® must be cleaned and disinfected before each use; this applies especially to the initial use after delivery.

11.1 Reusability

We guarantee 100 reprocessing cycles for the EndoCowboy® when used, reprocessed, and maintained correctly. Any further reuse or the use of damaged instruments is the responsibility of the user. Disregard of this instruction excludes any liability.

11.2 Cleaning and disinfection

First, the EndoCowboy® must be completely disassembled as described in the Assembly and disassembly of the EndoCowboy® chapter to ensure optimal cleaning and disinfection. For cleaning and disinfection, a washer-disinfector should be used in the Vario TD program.

When selecting the cleaning agent system, ensure that:

- it is generally suitable for cleaning products made of metals,
- if thermal disinfection is not used, an appropriate disinfectant with proven effectiveness (e.g., VAH/DGHM or FDA/EPA approval/clearance or CE marking) is used in addition, and that it is compatible with the cleaning agent used.

When selecting cleaning and disinfection agents, please ensure that the following components are not included:

- organic, mineral, and oxidizing acids (minimum allowable pH value 5.5),
- strong alkalis (maximum allowable pH value 11, neutral/enzymatic cleaner, lightly alkaline or alkaline cleaner recommended),
- organic solvents (e.g., alcohols, ethers, ketones, benzines),
- oxidizing agents (e.g., hydrogen peroxide),
- halogens (chlorine, iodine, bromine),
- aromatic/halogenated hydrocarbons.

The concentrations indicated by the manufacturer of the cleaning and disinfection solution must be strictly adhered to. Follow the instructions provided by the washer-disinfector manufacturer.

11.3 Inspection and Maintenance after cleaning/disinfection

After cleaning/disinfection visually inspect all parts for corrosion, damaged surfaces, chipping, deformities, and contamination, and remove damaged parts. Parts that are still dirty must be cleaned and disinfected again.

After cleaning and disinfection, the moving parts – adjusting wheel (2), threaded rod (4) and axial ball bearing (5) should be oiled with a suitable instrument oil (e.g. medicinal white oils; vapor-stable; free of oxidation and residue). This ensures the long operability and precise adjustment of the adjusting wheel during the application.

12. LassoTip Hygiene

The LassoTips are not delivered sterile. Before use, the LassoTip must be sterilized. We strongly recommend the use of a class B autoclave (121 °C, 1.1 bar, at least 20.5 min, gentle program). Use only sterile bags, according to standard NF EN 868, adapted to the lugs and the autoclave. Observe the instructions of the autoclave manufacturer. Ensure a clean and dry storage.

LassoTips are for single use only and should be disposed after use!

The flash sterilization method is not permitted. Additionally, do not use dry heat sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization, or plasma sterilization. To prevent staining and corrosion, the steam must be free of contaminants (see limits in DIN EN 13060). When sterilizing multiple products, the maximum load of the sterilizer must not be exceeded (follow the manufacturer's instructions).

13. Accessories

LassoTips in different sizes:

Due to the different sizes of the LassoTip

- 0.8 mm,
- 0.1 mm, and
- 0.12 mm

the loop size can be adapted to the particular case treatment.

14. Repairs

In the event of a malfunction, contact your local distributor or Koehrer Medical Engineering Customer Service. All repairs must be carried out with the manufacturer's approved spare parts and assemblies. For repairs, please send in the complete EndoCowboy®.

Make sure that the EndoCowboy® has completed the entire reprocessing process.

Please enclose with your return a document that briefly describes the error that occurred and that contains the complete personal data of the user. In the case of warranty claims, please enclose a copy of the invoice or the delivery note.

Return to:

Koehrer Medical Engineering Service
Adolf-Flecken-Strasse 10
41460 Neuss
Germany
Phone: +49 2131 1511717

Mail: info@endocowboy.com

15. Warranty

We grant a warranty of 12 months from date of invoice on this medical device. Any modification or addition to the product without the express permission of Koehrer Medical Engineering will void the warranty. Failure to observe the supplied technical instructions will invalidate the warranty. Koehrer Medical Engineering accepts no liability for damage or consequential damage resulting from normal wear and tear, improper use, cleaning or maintenance, failure to comply with regulations regarding use or commissioning, calcification, or corrosion, unusual or inconsistent with the user manual and other instructions of the manufacturer applications.

16. Disposal

The relevant statutory provisions regarding the disposal of medical waste apply.

Evidence of the medical device's basic suitability for effective automated disinfection was provided by an independent test laboratory using the Miele G7881 (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh, Germany) and the pre-cleaning and cleaning agent Neodisher FA Dental and the neutralizing agent Neodisher N (Dr. Weigert GmbH & Co. KG, Hamburg, Germany). The Vario TD program was considered in this regard.

Evidence of the medical device's basic suitability for effective steam sterilization was provided by an independent test laboratory using the steam sterilizer Melag Vacuklav 40-B.