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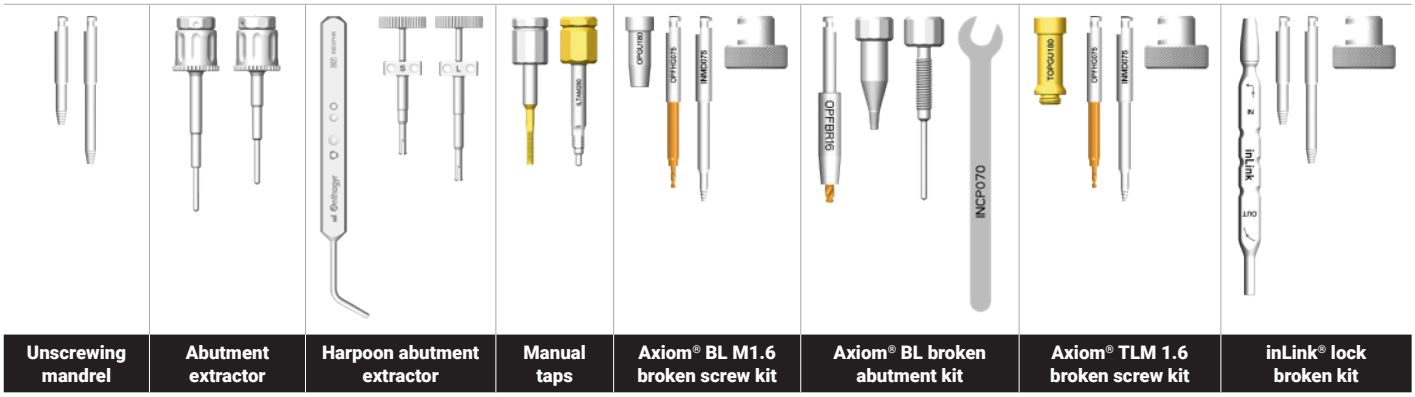
Rescue tools
Instruction for use



Unscrewing mandrel	Abutment extractor	Harpoon abutment extractor	Manual taps	Axiom® BL M1.6 broken screw kit	Axiom® BL broken abutment kit	Axiom® TLM 1.6 broken screw kit	inLink® lock broken kit

1. Product description

Rescue tools are part of the Axiom® Multi Level® system.

The unscrewing mandrel **INMDS** or **INMDL** is used to unscrew a prosthetic part with a damaged straight hexagonal recess.

The abutment extractor **INEXPS** or **INEXPL** is used to remove a screw-retained abutment stuck in Axiom® BL implant.

The harpoon abutment extractor kit **INEXPHSL-KIT** is used to remove a screw-retained abutment stuck or broken in Axiom® BL implant.

The manual taps **OPTAM16** and **ILTAM280** are used to conform damaged M1.6 thread and damaged M2.8 thread respectively.

The Axiom® BL M1.6 broken screw kit **INKITSCWBL** is used to remove a broken M1.6 thread from Axiom® BL implant.

The Axiom® BL broken abutment kit **INKITABTBL** is used to remove a broken screw-retained abutment from Axiom® BL implant.

The Axiom® TL M1.6 broken screw kit **INKITSCWTL** is used to remove a broken M1.6 thread from Axiom® TL implant.

The inLink® lock broken kit **INKITLOCK** is used to remove a broken inLink® lock from Axiom® TL implant or inLink® abutment and from the prosthesis.

The several kits contain a variety of rescue tools such as reworking drills, taps, keys etc.

Materials:

Rescue tools are made of Titanium (Ti6Al4V ELI), Stainless steels and high speed steel. Some of them are TiN coated (gold colour). Reworking drills are AlTiS coated (orange colour).

2. Intended use

The Rescue tools are intended to rescue an Anthogyr® implant system, where the prosthetic component is damaged or stuck, without removing an osseointegrated implant.

3. Indications

The Rescue tools are indicated for the removal of a damaged or stuck prosthetic component in patients with an osseointegrated implant.

4. Patient type and intended user

Rescue tools are intended for use with partially or totally edentulous adult patients who do not present any of the conditions listed among the contraindications.

Rescue tools are reserved for use by dental surgeons trained in implantology.

5. Contraindications

Allergy or hypersensitivity to chemical components in the materials used and mentioned in the "Product description" section.

6. Warning

- Products must be protected against inhalation or swallowing when handled in the mouth. Aspiration of products can lead to infection or incidental physical injury.
- Do not use damaged, corroded or dull tools. Always inspect tools before use.
- Do not exceed the maximum number of uses for the device as detailed in the "Lifespan of products" section.
- Reworking drills contain Cobalt which is classified as a hazardous substance.
- The direction of rotation and/or speed, particularly for reworking drills, must be respected.

7. Caution / Precaution

Clinical use:

- Single-use devices (reworking drills): do not reuse or do not re-sterilise. Risk of alteration of the functional surfaces.
- Inspect the tools before use. Never use potentially contaminated components. Only use properly reprocessed tools if they are suitable for multiple uses.
- Ensure that all handling is sterile.
- Check reworking drills proper hold in the contra-angle by pulling on it slightly.
- Handle cutting tools with care to avoid injury.

Component rework:

The component must not be retouched in any way.

8. Residual risks and side effects

The clinical outcome of dental treatment is influenced by multiple factors. The following residual risks and possible side effects are related to the use of Rescue tools and may lead to additional dental treatment at the dental practice:

Residual risks

- additional treatment at dentist's office
- bite / mastication / phonetic problems
- bleeding
- bone damage
- damage to adjacent/opposing tooth
- discomfort
- hypersensitivity / allergic reaction
- injuries of gingiva
- irritation / inflammation
- local or systemic infection (including peri-implantitis, periodontitis, gingivitis, fistula)
- local pain
- longer recovery / healing time than expected
- loss of implant
- loss of prosthetic component
- nerve damage possibly resulting in chronic pain
- paraesthesia, dysaesthesia
- poor aesthetic outcome
- possibility of prolongation of surgery
- possibility of surgical implant explantation
- possibility to swallow / inhale small parts during the procedure
- recall to the dentist's office
- sinus perforation

Side effects:

- swelling
- local inflammation
- bruising
- resorption of maxillary/mandibular ridge bone
- local infection
- minor bleeding

9. Compatibility information

Rescue tools are available in a wide variety of configurations. Only Anthogyr parts that are compatible with the other parts of the Anthogyr Dental implant system are suitable for use. For more information, please refer to the manuals listed in the "Further information" section.

Type of problem	Type of implant	Compatible Rescue tool
The screw-retained abutment (not broken) is stuck in the implant.	Axiom® Bone Level	INEXPS / INEXPL or INEXPHSL-KIT*
The screw-retained abutment is broken in the implant.		INEXPHSL-KIT** and, if unsuccessful, use INKITABTBL
The M1.6 screw is broken in the implant.	Axiom® Bone Level Axiom® Tissue Level	INKITSCWBL INKITSCWTL
The monobloc abutment is broken in the implant at the M1.6 level.		
The M1.6 tapping of the implant is damaged.		OPTAM16
The hexagonal recess*** is damaged.		INMDS / INMDL
The inLink® lock is broken.	Axiom® Bone Level + inLink® abutment Axiom® Tissue Level	INKITLOCK
The M2.8 tapping of the implant is damaged.	Axiom® Tissue Level	ILTAM280

**Especially for Angulated Access X-Base® abutments, Angulated Multi-Unit abutments and old generations of Axiom® Bone Level abutments which have no extraction thread.*

***INEXPHSL-KIT is the first option to be considered, as INKITABTBL is a more invasive solution (drilling of titanium in the patient's mouth, connection with a rotating power instrument).*

****Only hexagonal recess compatible with the straight hexagonal instruments.*

10. Cleaning and decontamination

Anthogyr rescue tools are delivered non-sterile. They must be cleaned and decontaminated before use and after each use for reusable components. Do not use the components if the packaging is opened or damaged. Before treatment, remove the components from their packaging. Anthogyr recommends following the protocol described in the cleaning and sterilization user guide available at ifu.anthogyr.com or on request from Anthogyr at the above address.

For sterilisation, see the "Sterilisation" section.

11. Sterilisation

Anthogyr rescue tools delivered non-sterile must be sterilised before use. Anthogyr recommends following the protocol described in the cleaning and sterilisation user guide available at ifu.anthogyr.com or on request from Anthogyr at the above address. After the sterilisation was done, asepsis rules must be followed.

Under no circumstances should a previously used or non-sterile instrument be placed in the patient's mouth. If the original packaging is damaged, Anthogyr will not accept the return of the content.

12. Protocol for use

Refer to the brochures listed in the "Further information" section for detailed step-by-step instructions.

Make sure to use the adapted rescue kit to the clinical situation to avoid damaging the components in mouth.

Specific to the Axiom® BL & TL M1.6 broken screw kit:

Make sure to use the compatible guide for drilling in order to avoid damaging the components in mouth.

Specific to the harpoon abutment extractor kit:

Before use in mouth, always make sure that the extractor Rod is pre-screwed into the extractor Body: the extractor Body (used alone) may get stuck in the abutment in mouth.

13. Lifespan of products

The component can be reused in accordance with the maximum number of uses defined in the table below, except in cases where there are signs of deterioration (illegibility of markings or markers, deterioration of the coating, signs of corrosion, etc.).

Type of device	Product lifespan
Reworking drills (OPFBR16, OPFHG075)	1 use
Unscrewing mandrels (INMDS, INMDL, INMD075)	10 uses
Broken abutment extractor (INEXPRBL)	
Harpoon abutment extractor (and contra-torque key)	10 uses
Manual taps (OPTAM16, ILTAM280)	20 uses
Guides (OPGU180, TOPGU180)	
Flat key (INCP070)	
Mandrel holder key (INCM)	50 uses
Abutment extractor (INEXPS, INEXPL)	250 uses

One use is equivalent to one reprocessing cycle.

14. Further information

For more information on the use of Anthogyr products, please contact your local Anthogyr sales representative or contact Anthogyr customer service or visit ifu.anthogyr.com and www.anthogyr.com.

For more specific information on the Rescue tools, please refer to:

- *Axiom® Multi Level® service set user guide (SSKIT_NOT)*
  Search code on ifu.anthogyr.com: INEXPS
- *Cleaning and sterilisation user guide (NETT-STE_NOT)*
  Search code on ifu.anthogyr.com: INEXPS
- *Axiom® Multi Level® Prosthetic user guide (AXIOM-MLP_NOT)*
  Search code on ifu.anthogyr.com: INEXPS

15. Storage

Store these products in a clean, dry area, at ambient temperature. Improper storage may compromise the essential characteristics of the materials and design, which may lead to device failure.

16. Waste treatment

Waste resulting from the intervention (packaging, part extracted, etc.) must be handled as medical waste under the responsibility of the user.

17. Information to be provided to the patient

Information on contraindications, warnings, precautions, side effects and complications with Anthogyr devices should be provided to the patient.

Patients must accept regular medical follow-ups and should consult their doctor in the event of any unexpected change in the performance of the prosthetic reconstitution.

Patients must be informed of the need to ensure regular oral hygiene.

18. Notes

The practitioner must have the necessary knowledge to practice dental implantology and must be familiar with the handling instructions for Anthogyr products as described in this document in order to use Anthogyr products safely and in accordance with their instructions for use.

Anthogyr products must be used in accordance with the manufacturer's instructions for use. The dental surgeon is solely responsible for the proper use of Anthogyr products in accordance with their instructions for use and to determine whether the product is suitable for the individual patient's situation.

Anthogyr products are part of a complete range and must be used in combination with the corresponding original components and instruments distributed by Anthogyr, its parent company and any affiliates or subsidiaries of the parent company ("Straumann"). The use of third-party products not distributed by Anthogyr voids any warranty or other obligation, express or implied, of Anthogyr.

Any product-related issues must be reported to the local Anthogyr organisation together with the product in question. In the event of a serious incident, the user must file a report with the local Anthogyr organisation and the appropriate competent authority in accordance with local regulations. Anthogyr also offers an online complaint service in the countries concerned.

19. Validity

The publication of this document supersedes and replaces all previous versions.

20. Availability

Some components of the Anthogyr implant system are unavailable in certain countries.

21. Symbols

The following table describes the symbols that may be printed on the packaging label. Please refer to the label on the packaging for the applicable product symbols.

Symbol	Description of symbol	Source of symbol
	Manufacturer	NF EN ISO 15223-1
	Date of manufacture	NF EN ISO 15223-1
	Catalogue number	NF EN ISO 15223-1
	Batch code	NF EN ISO 15223-1
	Serial number	NF EN ISO 15223-1
	Consult instructions for use or consult electronic instructions for use	NF EN ISO 15223-1
	Medical Device	NF EN ISO 15223-1
	CE marking - compliance with current regulations	Directive 93 / 42 / CEE ———— MDR (EU) 2017 / 745
	FDA certification logo	21 CFR 801.109(b) (1)
	Use-by date	NF EN ISO 15223-1
	Single sterile barrier system	NF EN ISO 15223-1
	Single sterile barrier system with protective packaging inside	NF EN ISO 15223-1

Symbol	Description of symbol	Source of symbol
	Sterilised using irradiation	NF EN ISO 15223-1
	Do not resterilise	NF EN ISO 15223-1
	Non-sterile	NF EN ISO 15223-1
	Sterilisable in a steam steriliser (autoclave) at temperature specified	ISO 7000 - 2868
	Non sterilisable in a steam steriliser (autoclave) at temperature specified	Anthogyr
	Do not use if packaging is damaged and consult instructions for use	NF EN ISO 15223-1
	Keep away from sunlight	NF EN ISO 15223-1
	Do not re-use	NF EN ISO 15223-1
	Caution	NF EN ISO 15223-1
	Contains hazardous substances	NF EN ISO 15223-1
	Screwing torque	Anthogyr
	Abutment extractor	Anthogyr
	Broken abutment extractor	Anthogyr
	Harpoon abutment extractor	Anthogyr