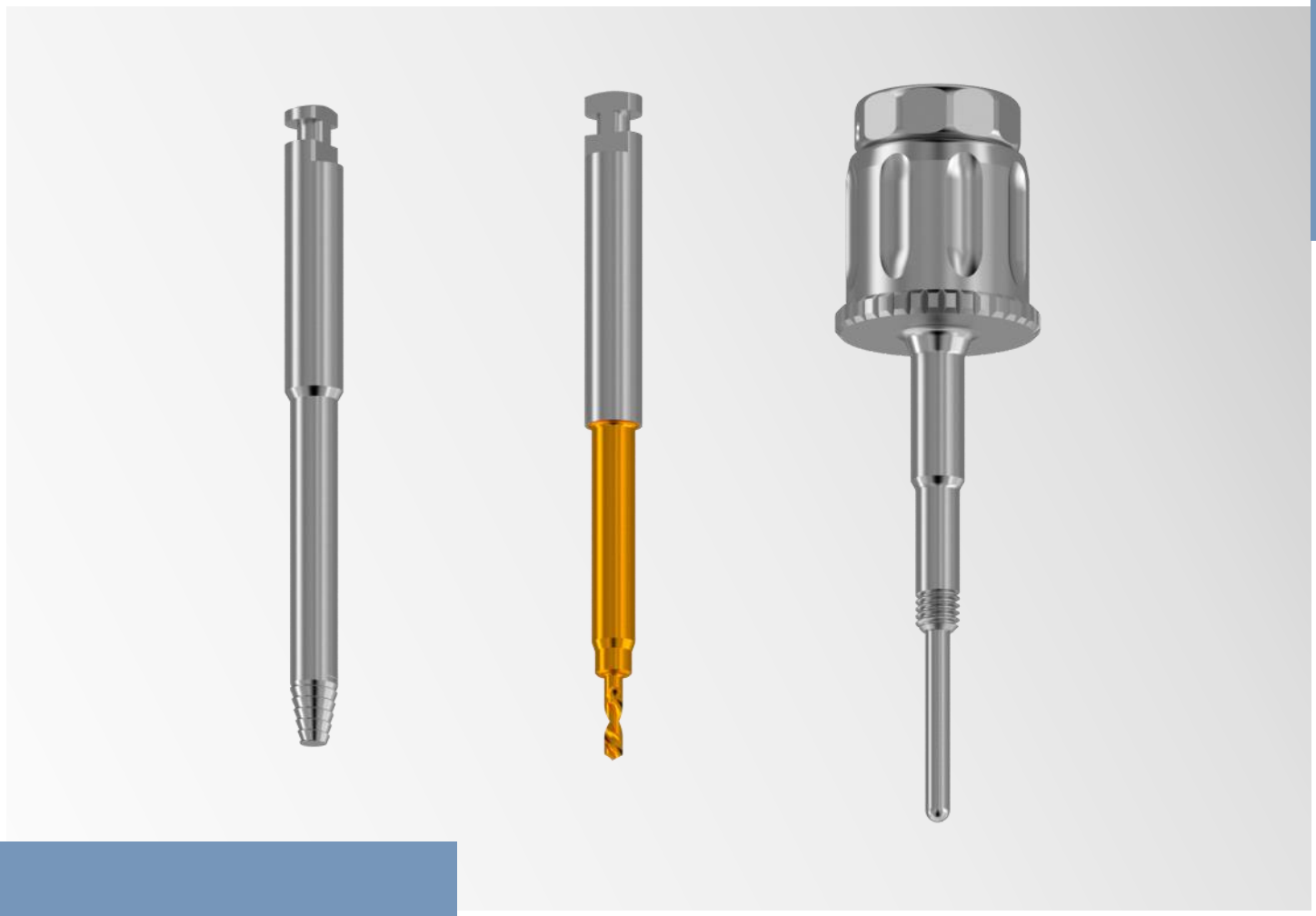
axiom® MULTI LEVEL®



Service Set

axiom® BL

Valid only in the United States

Anthogyr

A Straumann Group Brand

We would like to thank you very much for your trust and confidence as expressed in working with the Axiom® Multi Level® implant system.

Anthogyr offers various service solutions designed to solve problems encountered with the Axiom® Bone Level implant systems.

Success for you means success for us. Our marketing network and team of experts is completely available to you for any further information you may need.

Anthogyr

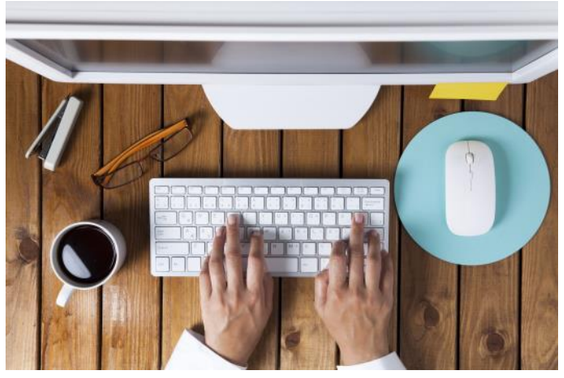
This instruction for use is not valid for OPKITRET, INKITEXPR kits.

These must be used according to the instructions for use available on the site ifu.anthogyr.com with search code: OPKITRET or INKITEXPR

INSTRUCTIONS AVAILABLE ONLINE

ifu.anthogyr.com

You can now find instructions for use (instructions and manuals) for **Anthogyr implants and prosthetics parts** in PDF format on our site ifu.anthogyr.com **using a PDF reader** (type Adobe Player).



HOW DOES THE SITE WORK?

This portal provides the latest instructions for using Anthogyr products.
To find the instructions for your device, please follow these steps:

1- Enter your product reference number, description or GTIN code (Global Trade Item Number) in the search field.

2- Press submit.

Your product's instructions will be available in PDF format, which you can consult online and/or print.

3- Select a language

Our instructions are available in several languages. To select the language you need, click the language choice menu.

This site is optimized for a 1024 x 768 px resolution screen to display instructions on PC or Mac with the following browser versions: Microsoft Internet Explorer 11 or higher, Safari 7.0 or higher (Mac only), Chrome 43 or higher, Firefox 38.0 and higher, and IOS and Android.

INFORMATION UPDATES:

Instructions for use are updated regularly and indicated by the "New" pictogram. Updated instructions can impact patient safety.
For this reason, we suggest you to avoid local back-ups and advise you to always check the Anthogyr portal.
To access archived instructions, click on "View old document versions".

You can also receive paper copies of instructions at no additional cost.
To receive paper copies, fill out the form available under the "Contact" tab or include a request with your next order.

Make sure to include your desired language.

The document will be delivered to you within 7 calendar days.

We are available if you have any comments or suggestions, via the "Contact" tab.

> Warnings and recommendations

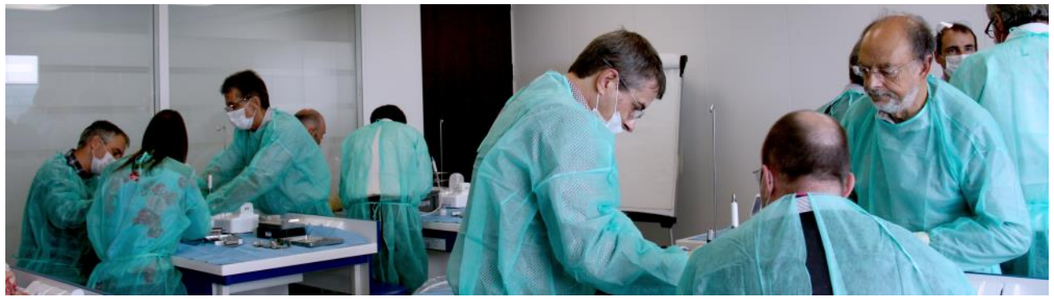
The instructions contained in this document describe the different phases of the surgical procedure and prosthetic restoration to be followed for the Axiom® Multi Level® implant system. A few general features specific to inserting implantable devices are recalled for information. This is not in any way an exhaustive document about implant and prosthetic practices to which the reader has any right of complaint.

TRAINING:

Axiom® Multi Level® components should only be used by practitioners who have been trained in implant practice and/or prosthetic techniques, and who are equipped for this type of procedure. Correct knowledge of surgical techniques and prosthetics is required to use this system. Specific training is offered and delivered at the Anthogyr company.

The surgical and prosthetic technique for the Axiom® Multi Level® system is performed exclusively in conjunction with the original components and instruments in accordance with the manufacturer's recommendations. Anthogyr can take no responsibility in case of placement non-compliant with this manual and in case of use of implants or prosthetic parts or instruments foreign to the system.

Clinical evaluation of the patient and the choice of treatment solution are the sole responsibility of the practitioner. The implant diameter and length must be determined beforehand by the dental practitioner, depending on the clinical situation. Patients should also be informed of potential risks associated with implanting this type of device: oedema, bruising, haemorrhage, periodontal complications, transient or permanent nerve damage, local or systemic infections or inflammation, bone fractures, loosening or fracture of the implant, dehiscence, aesthetic problems, aspirating or swallowing the device, iatrogenic trauma, etc.



EQUIPMENT:

The practitioner using the system is responsible for the follow-up and maintenance procedures required to identify and treat any complications as early as possible and for ensuring the correct functioning and safety of the device. The references and the batch numbers of all components implanted, temporarily and/or definitively, must be recorded in the medical file of the patient.

Follow-up and maintenance are part of the knowledge of a practitioner trained in placing dental implants.

The practitioner is also responsible for defining the different settings for his/her equipment (instrument rotation speed, irrigation flow rate, etc), according to each clinical case, and for confirming that these are in good condition before each procedure.

Reusable instruments must be cleaned, decontaminated and sterilised before each surgery (even when first used) in accordance with current protocols in hospitals and clinics. The organisation of the operating room, preparation of operating staff and of the patient (premedication, anaesthesia, etc...) should follow current procedures and are the responsibility of the practitioner.

Anthogyr can under no circumstances be held responsible for any harm arising from defective handling or use. In order to avoid swallowing or inhaling small components, it is recommended that these are rendered secure by fixing them to the outside of the mouth with a suture thread. Whenever an instrument is changed, confirm that the contra-angle or key are correctly fixed by applying slight traction and ensure that each part is correctly fixed onto the transfer system outside the oral cavity.

CONSERVATION:

In producing our products, we have paid particular care and guarantee that a manufacturing control has been performed on all products made available for sale. In order to guarantee their integrity, it is recommended that they be stored in their original packaging at an ambient temperature, away from moisture and direct sunlight.

Protect packages from dust and do not store in the same premises as solvents and/or paints containing solvents or chemical substances. The device must be used before the expiration date indicated on the traceability label.

If the package (blister-closure / bag) is damaged or a defect is apparent when the product is opened, it is imperative that the device not be used and that the nature of the defect, part numbers and batch numbers of the components concerned are re-ported to the distributor or to Anthogyr. The technical specifications contained within these instructions are provided for indicative purposes only and cannot form the subject of any complaint.

The Axiom® Multi Level® implant system must not be used on animals.

Single-use devices must not be reused, or resterilised (risk of contamination and risk of alteration of functional surfaces).

The instructions for use here in may only be reproduced or disseminated with prior approval from the Anthogyr company. Anthogyr reserves the right to vary the technical feature of its products and/or to make changes or improvements to the Axiom® Multi Level® system without prior notice.

The Axiom® Multi Level® implant system is not compatible with other Anthogyr and competitors' systems.

If uncertain, the user should contact the Anthogyr company before use.

This manual cancels and replaces all previous versions.

Explanations, symbols and diagrams

STERILE R	**Device sterilized by Gamma radiation**		**Do not re-use, single-use device**
LOT	**Manufacturing batch number of the device**		**Protect from light**
REF	**Commercial part number of the device**		**Do not use if packaging is damaged**
	Manufacturing date of the device		**Manufacturer**
	Expiration date of the device	CE/CE 0459	**Class I or Class IIa/IIb medical device complying with European Directive 93/42/CEE**
	Caution	25 N.cm	**Tightening torque**
NON STERILE	**Non-sterile device**	Rx ONLY	**U.S.federal law restrics this device to sale by or on the order of a dental professional.**
135°C	**Sterilizable in a steam sterilizer (autoclave) at temperature specified**		**Consult instructions for use or consult electro-nic instructions for use**
135°C	**Non sterilizable in a steam sterilizer (autoclave) at temperature specified**		

SUMMARY TABLE

axiom® BL

Step 1 *Identify the implant*	Step 2 *Identify the problem encountered*		Step 3 *Solution to be applied*	Step 4 *Protocol to follow page number*
	The hexagonal impression is damaged		INMDS or INMDL	9
	The abutment is stuck in the implant but remains intact		INEXPS or INEXPL	11
	The M1.6 tapping of the implant is damaged		OPTAM16	10
	The M1.6 screw is broken in the implant		INKITSCWBL	13
	The abutment is broken in the implant	**Single-component** abutment	The abutment is broken at the M1.6 threading	INKITSCWBL — 13
		Screw-retained abutment. Was the screw removed intact ?	YES	INKITABTBL — 15
			NO	INKITABTBL and INKITSCWBL — 15 + 13

The various KITS

Service solutions for Axiom® BL implants are available depending on the analysis of the clinical case:
- → Accurate knowledge of the problem: please refer to the **SUMMARY TABLE** to order the most suitable solution.
- → Knowledge of the implant system only: order the Services SET(s) listed below.

⚠ All the KITS are supplied **non-sterile**, they must be cleaned and sterilised according to the cleaning and sterilisation manual available at ifu.anthogyr.com *(search code: INEXPS for example).*

1. KIT to be used in combination with an Axiom® BL implant

INKITSCWBL
BL M1.6 BROKEN SCREW KIT

INKITABTBL
BL BROKEN ABUTMENT KIT

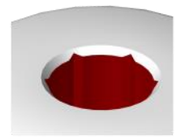
INEXPS / INEXPL
S/L ABUTMENT EXTRACTOR

INMDS / INMDL
S/L UNSCREWING MANDREL

OPTAM16
M1.6 X 0.35 TAP

→ INKITSSBL
AXIOM® BL SERVICE SET

INMDS / INMDL - S / L unscrewing mandrel



Indication:
Remove a prosthetic part / screw with a damaged hexagonal impression.

Composition:

S unscrewing mandrel
INMDS [1]

L unscrewing mandrel
INMDL [1]

[1] *For best performance and clinical results, we recommend not using these components for more than 10 times each.*

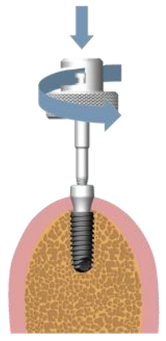
Materials required in addition to the KIT:

Mandrel holder key
INCM

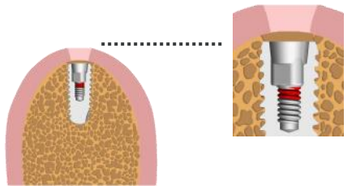
Protocol:

Step 1: Clean and sterilise the instruments.
Clean the hexagonal impression.

Step 2: Use the INMDS or INMDL unscrewing mandrel with the INCM manual wrench to hook the hexagonal impression to unscrew the screw: turn **counterclockwise** while applying pressure.



OPTAM16 - Tap M1.6 x 0.35



Indication:
Conform the damaged M1.6 tapping of an Axiom® BL

Composition:

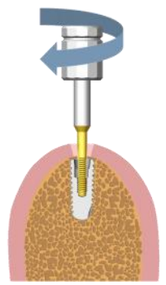
Tap M1.6 x 0.35
OPTAM16 [1]

[1] *For best performance and clinical results, we recommend not using these components for more than 10 times each.*

Protocol:

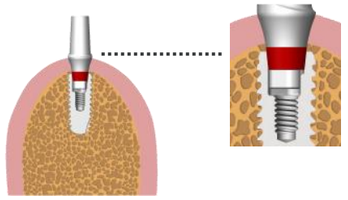
Step 1: Clean and sterilise the instruments.
Clean the hexagonal impression.

Step 2: While taking care to remain in the implant axis, tap gradually without forcing. After each half turn, unscrew the tap a quarter turn. Unscrew the tap regularly to clean it.



Step 3: Thoroughly clean the implant connector before inserting a new prosthetic part.

INEXPS / INEXPL - Abutment Extractor S / L



Indication:
Remove an abutment stuck in an Axiom® BL implant (the abutment must not be broken).

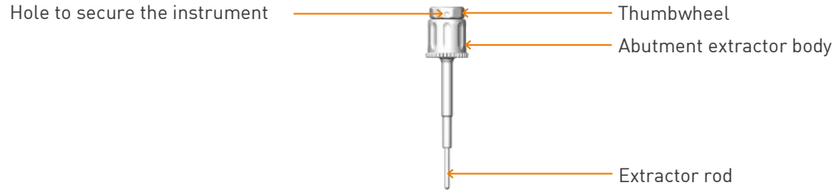
If the abutment is broken, please refer to the ***SUMMARY TABLE*** *to determine the service SET to be used.*

Composition:

S abutment extractor
INEXPS [1]

L abutment extractor
INEXPL

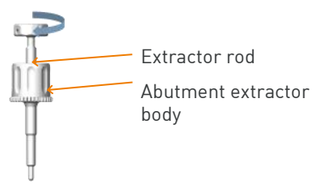
[1] *Instrument supplied in the INM0DOPP3 kit.*

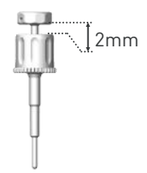


Protocol:

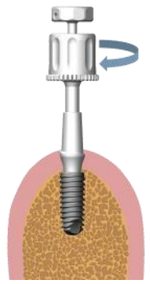
Step 1: Clean and sterilise the body and the rod.

Step 2: Assemble the rod in the body of the extractor leaving a gap of 2mm (approx.) between the head and the thumbwheel.

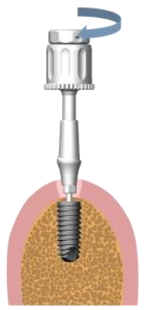




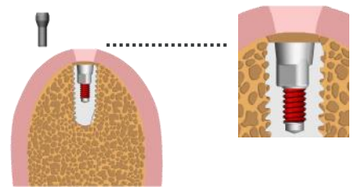
Step 3: Screw the instrument using the extractor body.



Step 4: Screw the thumbwheel until it presses against the body of the extractor to allow the removal of the abutment .



INKITSCWBL - KIT screw M1.6 BL broken



Indication:

→ Remove a broken M1.6 screw (in the case of a screw-retained abutment) in an Axiom® BL implant.

→ Remove a single-component broken abutment at the M1.6 threading in an Axiom® BL implant.

Composition:

Axiom® BL Ø1.80 service guide
OPGU180

Ø0.75 left helicoidal drill
OPFHG075 [2]

mandrel holder key
INCM

unscrewing mandrel Ø0.75
INMD075 [1]

[1] *For best performance and clinical results, we recommend not using these components for more than 10 times each.*

[2] *This is a **single-use** component.*

Equipment required in addition to the KIT:

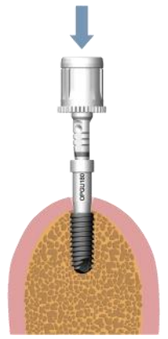
manual key
OPCV060 [3]*-OPCV110-OPCV160* [3]

[3] *These instruments are supplied in the INMODOPS3 kit.*

Protocol:

Step 1: Clean and sterilise the instruments.
Clean the implant connector.
Lubricate the implant connector with water.

Step 2: Place the OPGU180 guide in the implant using an implant wrench *(Ref.OPCV060,OPCV110,OPCV160)* by exerting pressure to wedge it in the taper of the implant. Remove the implant wrench **while maintaining the guide in place**.

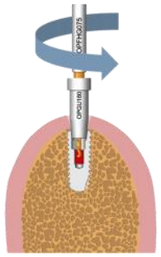


Step 3: Compress the OPGU180 guide.

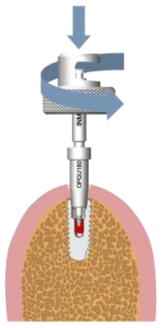
⚠ **Ensure that the guide is well anchored in the implant.**

Lubricate the inner bore of the guide with water.

Step 4: Once the guide is in place, position the drill in the guide and then drill progressively (removing the shavings progressively) with the OPFHG075 drill **counterclockwise** at a speed of 3000 rpm until it stops. If the screw does not come with the drill, go to step 4.

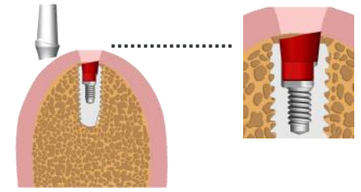


Step 5: With the guide still in place, use the INMD075 unscrewing mandrel with the INCM wrench to hook the screw in the previously drilled Ø0.75 hole: turn **counterclockwise** while applying pressure.



Step 6: Thoroughly clean the implant connector before inserting a new prosthetic part.

INKITABTBL - Broken BL Pillar KIT



Indication:
Remove a broken screw-retained abutment in an Axiom® BL implant (abutment broken level with the neck of the implant).

If a single-component abutment is broken in an Axiom® BL implant, use the INKITSCWBL KIT (p.13).

Composition:

retouch stop drill 1.6 mm
OPFBR16 [2]

Push rod + Extractor
INEXPRBL [1]

stainless steel flat wrench 7 mm
INCP070

[1] For best performance and clinical results, we recommend not using these components for more than 10 times each.

⚠ *[2] This is a **single-use** component.*

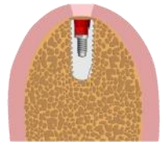
Protocol:

Step 1: Clean and sterilise the instruments.

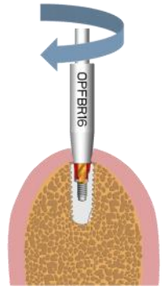
If the abutment is broken above the top of the implant, smooth out the surface of the abutment without damaging the implant.

If the abutment is broken below the top of the implant, do not adjust the abutment.

Clean the area with water and air.

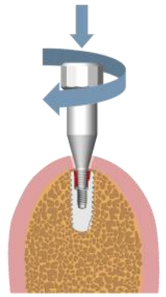


Step 2: In the implant axis, under **irrigation,** drill with the OPFBR16 drill in a clockwise direction at a speed of 3000 rpm until it stops.

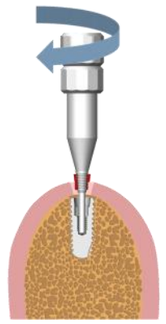


Step 3: Screw the extractor into the abutment while applying pressure. If required, finish tightening with the INCP070 wrench.

Ensure that the extractor is well anchored in the broken abutment.



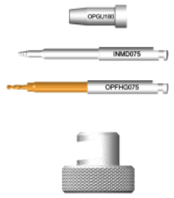
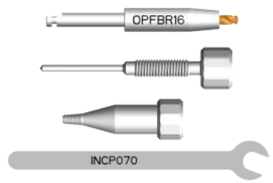
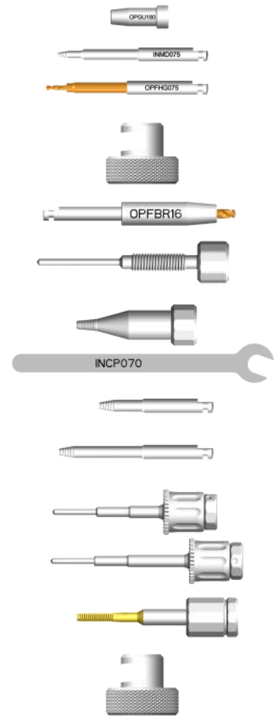
Step 4: Screw the push rod as far as it will go in order to extract the abutment end attached to the extractor. If required, finish tightening with the INCP070 wrench.



Step 5: Thoroughly clean the implant connector before inserting a new prosthetic part.

If the M1.6 screw is broken in the implant, proceed with removing this screw using the INKITSCWBL KIT (p.13).

Component part numbers

AXIOM® BL KIT		REFERENCES
	**BL M1.6 broken screw KIT** Includes: - 1 Axiom® BL Ø1.80 guide - 1 unscrewing mandrel for Ø0.75 - 1 Ø0.75 left helicoidal drill - 1 mandrel holder key	**INKITSCWBL**
	**BL broken abutment KIT** Includes: - 1 retouch stop drill 1.6 mm - 1 push rod - 1 extractor - 1 stainless steel flat wrench 7 mm	**INKITABTBL**
	**Axiom® BL service SET** Includes: - the components of the INKITSCWBL KIT - 1 Axiom® BL Ø1.80 guide - 1 Ø0.75 left helicoidal drill - 1 unscrewing mandrel for Ø0.75 - 1 mandrel holder key - the components of the INKITABTBL KIT - 1 retouch stop drill 1.6 mm - 1 push rod - 1 stainless steel flat wrench 7 mm - 1 extractor - 1 S unscrewing mandrel - 1 L unscrewing mandrel - 1 S abutment extractor - 1 L abutment extractor - 1 M1.6 x 0.35 tap - 1 mandrel holder key	**INKITSSBL**

NOTES

NOTES

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