

AXIUM IMPLANT SCREW DRIVERS SETS

Instructions for Use (IFU)



DEVICE DESCRIPTION

Axium Implant Screw Driver Set is intended to provide a complete solution for all dental requirements.

The Axium screwdrivers are made from a carefully selected grade of stainless steel that allows heat treatment to improve strength and maintain corrosion resistance. Special passivation processes enrich the chrome content of the surface of each driver to maximise corrosion resistance.

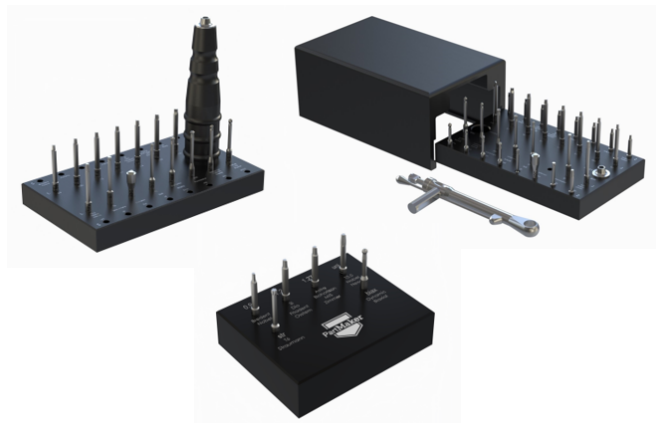


Figure 1 Axium Family Products

All Axium drivers use regular RA latch grip connection (ISO 1797) for universal use in handpieces, ratchets, and the unique laboratory handle further expands the use of the set. Clinical use ratchet hubs machined from Grade 5 Titanium and equipped with a Sure-Seat connector to ensure a positive seat for each driver. DECOGRIP laboratory handles allow use as conventional laboratory driver. The ergonomic groove shape rests comfortably in the hand for fast rotation and universal use, KITS ARE IDEAL FOR USE AS: Clinic ` Laboratory use Laboratory Loaner Promotional Gift Teaching aid OEM.

High Strength Made from medical grade stainless steel. Rated to 55 HRC. Laser Etched Sizes Each driver is laser marked for easy identification, and the blocks are labelled for compatibility. No more sifting through kits to find the correct size. TGA REGISTERED for Dental Applications For the removal and tightening of: Healing

caps Cover screws MultiUnit Abutments Guide pins
Cross-pin screws Scanbody screws

The System includes mainly an Aluminium base and a number of drivers made from Heat treated stainless steel.

The product comes in various varieties:

Axium Premium Implant Drivers Set
Axium Lab Implant Drivers Set
Axium Mini Implant Drivers Set

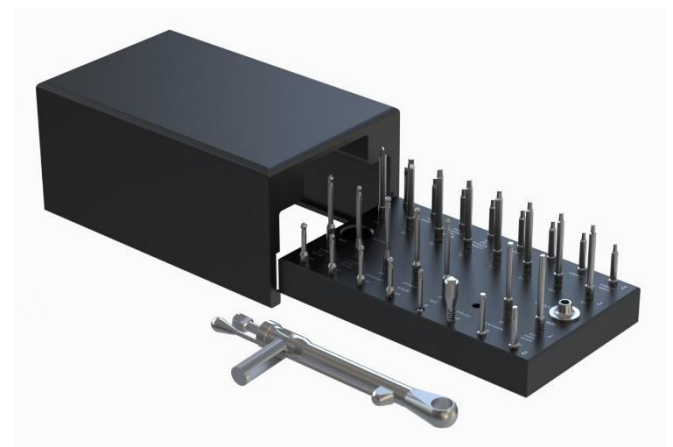


Figure 2 Axium Premium Implant Screw Driver Sets

Axium Premium Implant Screw Drivers Set

The Set comes with:

- 1 X Aluminium Set Base
- 1 X Aluminium Set Lid
- 31 X Screw Drivers
- 1 X Torque Wrench Adapter
- 1 X Torque Wrench

Available in Black, Blue, Gold, Purple & Grey.

Table 1 Axium Premium Screw Drivers List

Shape	Description
Hexagon	Hexagonal socket screws 0.9mm, 22 mm length
	Hexagonal socket screws 0.95mm, 22 mm length
	Hexagonal socket screws 1.0mm, 22 mm length
	Hexagonal socket screws 1.1mm, 22 mm length
	Hexagonal socket screws 1.2mm, 22 mm length
	Hexagonal socket screws 1.27mm, 22 mm length

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	Hexagonal socket screws 0.9mm, 32 mm length
	Hexagonal socket screws 0.95mm, 32 mm length
	Hexagonal socket screws 1.0mm, 32 mm length
	Hexagonal socket screws 1.1mm, 32 mm length
	Hexagonal socket screws 1.2mm, 32 mm length
	Hexagonal socket screws 1.27mm, 32 mm length
Hexagon Ball	Hexagonal socket screws, 1.38mm, 22 mm length
	Hexagonal socket screws, 1.65mm, 22 mm length
	Hexagonal socket screws, 1.38mm, 32 mm length
	Hexagonal socket screws, 1.65mm, 32 mm length
Hexalobular	Torx® and Stardrive®, T5.5, 32 mm length
	Torx® and Stardrive®, T6, 32 mm length
	Hexalobular socket screws, ex 1.72mm, 32 mm length
	Torx® and Stardrive®, T5, 22 mm length
	Torx® and Stardrive®, T5, 32 mm length
	Torx® and Stardrive®, T5.5, 22 mm length
	Torx® and Stardrive®, T6, 22 mm length
	Hexalobular socket screws, 1.72mm, 22 mm length
Pentalobe	Pentalobular socket screws, 1.63mm, 22 mm length
	Pentalobular socket screws, 1.63mm, 32 mm length
Square	Square socket screws, Sqr 1.3, 32 mm length
	Square socket screws, Sqr 1.3, 22 mm length
Slot	Slot screws, 0.7mm, 22 mm length
	Slot screws, 0.7mm, 32 mm length
Triangle	Locator, Triangle 2.3 mm, 22 mm length



Figure 4 Axium Lab Implant Screw Driver Sets



Figure 5 Lab Handle

Compatible Ratchets

The following ratchet are compatible with the system:
Neoss, Straumann, Astra, DIO, Dentis, Osstem.



Figure 3 Compatible Torque Wrench Adapters

Axium Lab Implant Screw Drivers Set

The Set comes with:
1 X Aluminium Set Base (BLK/BLU/G/P/GRY)
16 X Screw Drivers
1 X Lab Handle
Available in Black, Blue, Gold & Purple.

Table 2 Axium Lab Screw Drivers List

Shape	Description
Hexagon	Hexagonal socket screws 0.9mm, 32 mm length
	Hexagonal socket screws 0.95mm, 32 mm length
	Hexagonal socket screws 1.0mm, 32 mm length
	Hexagonal socket screws 1.1mm, 32 mm length
	Hexagonal socket screws 1.2mm, 32 mm length
	Hexagonal socket screws 1.27mm, 32 mm length
Hexagon Ball	Hexagonal socket screws, 1.38mm, 32 mm length
	Hexagonal socket screws, 1.65mm, 32 mm length
Hexalobular	Torx® and Stardrive®, T5.5, 32 mm length
	Torx® and Stardrive®, T6, 32 mm length
	Hexalobular socket screws, ex 1.72mm, 32 mm length
	Torx® and Stardrive®, T5, 32 mm length
	Torx® and Stardrive®, T5.5, 22 mm length
Pentalobe	Pentalobular socket screws, 1.63mm, 32 mm length
Square	Square socket screws, Sqr 1.3, 32 mm length
Slot	Slot screws, 0.7mm, 32 mm length
Triangle	Locator, Triangle 2.3 mm, 32 mm length

Axium Mini Implant Screw Drivers Set

The Set comes with:
1 X Aluminium Set Base (BLK)
6 X Screw Drivers
Available in Black Only.

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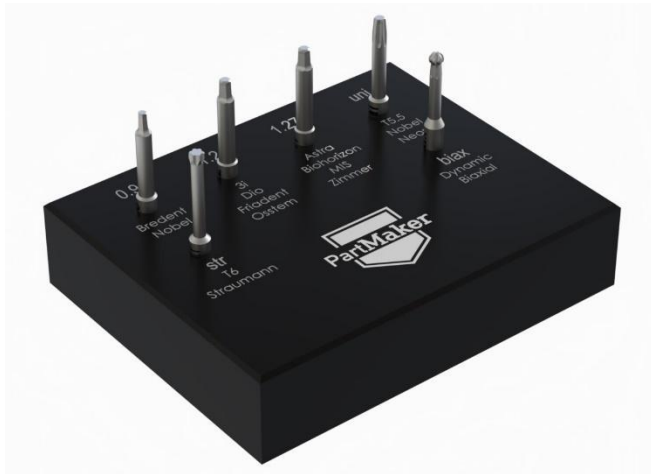


Table 3 Axium Mini Screw Drivers List

INDICATION FOR USE

Table 4 Implant Systems Covered

CONTRA INDICATIONS

- Patients in whom adequate size, number or desirable position of the implants are not attainable to achieve safe support of functional or parafunctional loads.
- Patients who are medically unfit for this procedure.

The risks and complications with prosthetic components, include but are not limited to the following:

- Allergic reaction to material.
- Patients may swallow or aspirate components that are not secured.
- Application of excessive torque may cause the fracture of an abutment/screw.
- Screws may loosen

Provided non-sterile reusable. Non Sterile parts must be cleaned and sterilized prior to clinical use, according to the dental clinic standard for disinfection & sterilization procedure.

Sterilization: The recommended process is based on [ADA Digital Sterilization Guidelines](#).

Axiom Implant Screw Driver Set components are manufactured by PartMaker Pty Ltd and are compatible with the following systems:

Table 5 Implant Compatibility

Implant Manufacturer	Restorative Platform
Straumann	SRA, WN, RN, NN, NNC, NC, RC
Astra	3.0EV, 3.6EV, 4.2EV, 4.8EV, 5.4EV, 3.5/4.0, 4.5/5.0
MIS	MIS MUA, 3.0, 3.5, 4.5, 5.7, MIS C1, NEOSS
Nobel	3.4, NP3.5, RP4.1, RP5.0, WP5.0, RP MUA, WP MUA

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MATERIALS & USAGE

Axiom Implant Screw Driver Set components materials of construction are shown in table-6 below.

Table 6 System Components

Component	Part No.	Material	Usage
Set Base	IDS	Al 6061	Reusable
Set Lid	IDSL	Al 6061	Reusable
Screw Drivers	DVR	SS 431HT	Reusable
Torque Wrench Adaptor	DVR	Ti-6Al-4V ELI.	Reusable
Torque Wrench	TR	SS 304	Reusable

resulting from treatment outside of our control. The responsibility rests with the clinician.

Prosthetics components are small and special care should be taken to prevent swallowing or choking. Use instruction for use for handling instructions.

LABELS

PartMaker Labels comply with ISO 15223-1 medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements.

MANUFACTURER

PartMaker Pty Ltd (ISO 13485 Certified)
ACN 163 459 667
1/11 Korong Road, Heidelberg West VIC 3081
Tel. 03 9650 2033
www.partmaker.com.au

RECOMMENDED TORQUE

The table below highlights the maximum torque level for each thread size as a guidance only, Device user should comply to the Implant Systems manufacturer for exact data.

Table 7 Recommended Torque for Thread sizes

Thread Size	Maximum Torque (N.Cm)
M 1.4	15
M 1.6	20
M 1.8	25
M 2.0	25
M 2.5	25
1-72	25

All PartMaker products are manufactured in accordance with ISO 13485 and bare the TGA requirements ([ARTG 304699](http://www.artg.gov.au/artg304699)). Photographs of the products are for information purposes only. The type, reference and connection of each element should be checked. Some PartMaker items may not be available in your country. These instructions replace all previous editions. For any detailed information about PartMaker products please contact us via sales@partmaker.com.au

DISPOSAL

Dispose of any components that are not to be reprocessed according to Clinic Sharps disposal protocol.

WARNINGS AND PRECAUTIONS

The guidelines presented herein are not intended to substitute for formal clinical or laboratory training. PartMaker devices should only be used by individuals with training and experience to their clinically accepted application. PartMaker is not liable for damages

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