SOUTHERNIMPLANTS®
Innovative Treatment Solutions

English	INSTRUCTIONS FOR USE: Southern Implants® Implant Insertion Tools: Handpiece Latch and Wrench inserts
Español	INSTRUCCIONES DE USO: Southern Implants® Implant Insertion Tools: Handpiece Latch and Wrench inserts
Italiano	ISTRUZIONI PER L'USO: Southern Implants® Implant Insertion Tools: Handpiece Latch and Wrench inserts
Français	MODE D'EMPLOI : Southern Implants® Implant Insertion Tools: Handpiece Latch and Wrench inserts
Deutsch	GEBRAUCHSANWEISUNG: Southern Implants® Implant Insertion Tools: Handpiece Latch and Wrench inserts
Português	INSTRUÇÕES DE UTILIZAÇÃO: Southern Implants® Implant Insertion Tools: Handpiece Latch and Wrench inserts

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Intended Use
Southern Implants® implant insertion tools are intended to be used to pick up the implant from the sterile packaging and carry the implant to the prepared osteotomy for implant placement.

Intended user
Maxillo-facial Surgeons, General Dentists, Orthodontists, Periodontist, Prosthodontists and other appropriately trained and experienced implant users.

Intended environment
The instruments are intended to be used in a clinical environment such as an operating theater or a dentist consultation room.

Intended patient population
This device is used in the dental restoration of partially or fully edentulous patients in the upper or lower jaw. Restorations may comprise single teeth, partial or full bridges, and may be fixed or removable.

Description
Southern Implants insertion tools are reusable instruments which are used in conjunction with Southern Implants 5 Implant connections. These handpiece and wrench tools are available in various lengths. All implant insertion tools are provided non-sterile.

The handpiece versions have a Latch dimension compatible to ISO 1797. This is in order to connect the insertion tools to the handpiece of an implant motor unit.
Handpiece tools are available in:

- The standard version, has a W&H hex on the shaft, this allows the handpiece to drive on the W&H hex as well as the latch.
- A Universal version, which does not feature a W&H hex on the shaft, the handpiece will drive on the latch only.

The wrench versions have a square connection, to be used with the I-WI-SS wrench converter connected to the Southern Implants torque wrench(I-TWS-B45/B100).

Indications for use
Implant insertion tools are indicated for use in conjunction with implants in order to: pick-up the implant from the sterile packaging, carry the implant to the prepared osteotomy, and to place the implant into the prepared osteotomy.

Contraindications
Do not use in patients:

- who are medically unfit for dental implant procedures
- where adequate numbers of implants could not be placed to achieve full functional support of the prosthesis,
- who are allergic or have hypersensitivity to pure titanium or titanium alloy (Ti-6Al-4V), gold, palladium, platinum or iridium.
- who are under the age of 18, have poor bone quality, blood disorders, infected implant site, vascular impairment, uncontrolled diabetes, drug or alcohol abuse, chronic high dose steroid therapy, anti-coagulant therapy, metabolic bone disease, radiotherapy treatment.

Warnings
THESE INSTRUCTIONS ARE NOT INTENDED AS A SUBSTITUTE FOR ADEQUATE TRAINING.

- For the safe and effective use of dental implants, it is suggested that specialised training be undertaken, including hands-on training to learn proper technique, biomechanical requirements and radiographic evaluations.
- Responsibility for proper patient selection, adequate training, experience in the placement of implants, and providing appropriate information for informed consent rests with the practitioner. Improper technique can result in implant failure, damage to nerves/vessels and/or loss of supporting bone.
- The use of non-sterile items can lead to secondary infections of the tissue or transfer infectious diseases.

Cautions
New and experienced Implant users should do training before using a new system or attempt to do a new treatment method. Take special care when treating patients who have local or systemic factors that could affect the healing of the bone and soft tissue, i.e poor oral hygiene, uncontrolled diabetes, are on steroid therapy, smokers, infection in the nearby bone and patients that had oro-facial radiotherapy.

Thorough screening of prospective implant candidates must be performed including:

- A comprehensive medical and dental history.
- Visual and radiological inspection to determine adequate bone dimensions, anatomical landmarks, occlusal conditions and periodontal health.
- Bruxism and unfavourable jaw relations must be taken into account.
- Proper pre-operative planning with a good team approach between well-trained surgeons, restorative dentists and lab technicians is essential for successful implant treatment.
- Minimizing the trauma to the host tissue increases the potential for successful osseointegration.
- Electro-surgery should not be attempted around metal implants, as they are conductive.

During surgery
Care must be taken that parts are not swallowed during any of the procedures, a rubber-dam application is recommended when appropriate. Care must be taken to apply the correct implant insertion torque values.

Post-surgery
Regular patient follow-up, and proper oral hygiene must be achieved to ensure favourable long-term results.

Clinical procedures
A proper clinical and radiological evaluation must be done to determine the bone dimensions and bone quality. Ensure that all instruments are in a good condition.

Instrument Compatibility, Information and Surgical Procedures

Implants supplied with a fixture mount attached to the implant, will use a latch implant insertion tool referred to as a "Connector to Handpiece" (I-CON-X & I-CON-IT).
Implants supplied without a fixture mount attached to the implant, will use an implant connection specific latch insertion tool referred to as an "Insertion tool"

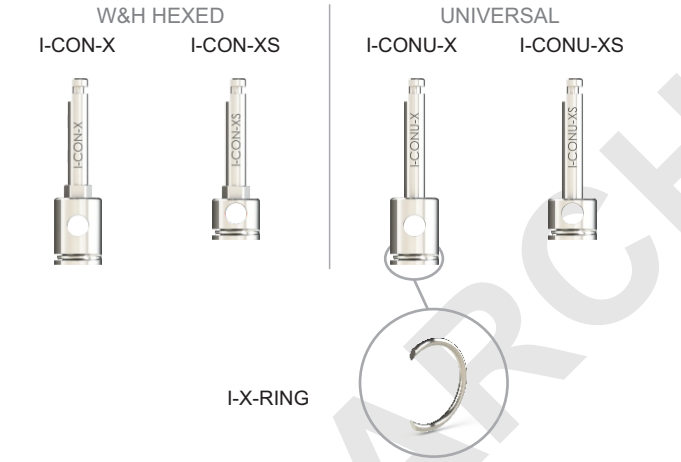
These **notes** apply to Southern Implants Implant insertion tools:

- Connect the insertion tool "latch" to the handpiece. If the latch is not inserted fully into the handpiece the torque is applied to the latch, resulting in possible twisting of the latch or damage to the handpiece. Consult the instructions for use of the handpiece to ensure proper engagement of the latch.
- Do not apply more than 40-45Ncm to any latch type instrument, this could cause damage to the handpiece and/or latch.
- Do not use the handpiece to manually torque the implant, after the initial placement, especially not once it is switched off. Disengage from the handpiece and continue with a wrench insertion tool.
- Do not use implant insertion tools with any drill extension, this will result in deformation of the latch, and damage to the drill extension.
- Excessive manual torque (>70Ncm with the wrench should be avoided, as this will cause too much compression in the bone or damage to the implant. A torque exceeding the maximum limit indicates that the implant should be retrieved and additional drilling should be performed in the site.

EXTERNAL HEX implants

Implants are pre-mounted with a fixture mount attached to the implant, the connector to handpiece is used. *(Fig. 2)*

CONNECTOR TO HANDPIECE *(Fig. 1)*



The I-CON-* is supplied with a retention ring (I-X-RING) that functions like a circlip *(Fig. 1)*. This ring is also sold separately.

Care must be taken when cleaning the instrument to not accidentally remove or damage the I-X-RING. This results in non-retention when picking up the implant.

Replacing the I-X-RING:

- Use a sharp instrument and apply slight pressure on the open side of the I-X-RING. Rotate the I-X-RING to remove it.
- Take a new I-X-RING and clip it into the dedicated groove on the I-CON-*.
- Ensure that the I-X-RING is still clipped in the dedicated space on the I-CON-*.
- Ensure that the closed side of the ring is positioned over the retention window.
- If the ring has moved during cleaning, use a sharp tool / instrument to rotate the ring to engage the retention opening.

Compatible implants

(Fig. 2)

EXTERNAL HEX — **ZYGOMATIC AND ONCOLOGY**

	CODE	LENGTHS	MSc
Ø4.3 with Ø3.4 apex	ZYGAN	30 / 35 / 37.5 / 40 / 42.5 / 45 / 47.5 / 50 / 52.5 / 55 / 60	√
	ZYGEX	30 / 35 / 37.5 / 40 / 42.5 / 45 / 47.5 / 50 / 52.5 / 55	√
Ø4.3	ZYG-55	35N / 37.5N / 40N / 42.5N / 45N / 47.5N / 50N / 52.5N / 55N / 60N	√
	ONC-55	27.5N / 32.5N / 37.5N / 42.5N / 47.5N	√

Prosthetic platform angled at 55°
Supplied with fixture mount.

EXTERNAL HEX — Straight Implants

	CODE	LENGTHS	MSc	
Ø3.0	IP-	8.5 / 10 / 11.5 / 13 / 15	√	Tapered
Ø3.25	IBN	8.5 / 10 / 11.5 / 13 / 15 / 18		Cylindrical
	IBNT	8.5 / 10 / 11.5 / 13 / 15 / 18	√	Tapered
Ø3.75	IBS	7 / 8.5 / 10 / 11.5 / 13 / 15 / 18 / 20	√	Cylindrical
Ø4.0	IBT	6 / 8.5 / 10 / 11.5 / 13 / 15 / 18	√	Tapered
	IET	4		Tapered
Ø5.0	BA	6 / 7 / 8.5 / 10 / 11.5 / 13 / 15 / 18	√	Cylindrical
	BAT	6 / 8.5 / 10 / 11.5 / 13 / 15 / 18	√	Tapered
Ø6.0	BBBT	6 / 8.5 / 10 / 11.5 / 13 / 15 / 18		Tapered

Supplied with fixture mount.

EXTERNAL HEX INVERTA® — Straight Implants

	CODE	LENGTHS	
Ø3.5 - Ø4.5	IV-EX35-45	10 / 11 / 13 / 15 / 18	Tapered
Ø4.0 - Ø5.0	IV-EX40-50	10 / 11 / 13 / 15 / 18	Tapered
Ø5.2 - Ø6.0	IV-EX52-60	10 / 11 / 13 / 15	Tapered

Supplied with fixture mount.

EXTERNAL HEX — Co-Axis®

	CODE	LENGTHS	MSc	
Ø3.25	IBNT12d	8.5 / 10 / 11.5 / 13 / 15 / 18	√	Tapered
Ø4.0	IBR12d	8.5 / 10 / 11.5 / 13 / 15 / 18	√	Tapered
	IBR24d	8.5 / 10 / 11.5 / 13 / 15 / 18 / 20 / 22 / 24	√	Tapered
Ø5.0	BAR12d	8.5 / 10 / 11.5 / 13 / 15 / 18	√	Tapered
	BAR24d	8.5 / 10 / 11.5 / 13 / 15 / 18	√	Tapered
	BAR36d	8.5 / 10 / 11.5 / 13 / 15 / 18 / 20 / 22 / 24	√	Tapered
Ø6.0	BBBT12d	10 / 11.5 / 13 / 15 / 18		Tapered
	BBBT24d	10 / 11.5 / 13 / 15 / 18		Tapered

Prosthetic platform angled at 12°, 24°, 36°
Supplied with fixture mount.

EXTERNAL HEX INVERTA® — Co-Axis®

	CODE	LENGTHS	
Ø3.5 - Ø4.5	IV-EX3512D-45	11 / 13 / 15 / 18	Tapered
Ø4.0 - Ø5.0	IV-EX4012D-50	11 / 13 / 15 / 18	Tapered
Ø5.2 - Ø6.0	IV-EX5212D-60	11 / 13 / 15 / 18	Tapered

Prosthetic platform angled at 12°
Supplied with fixture mount.

EXTERNAL HEX — MAX

	CODE	LENGTHS	MSc	
Ø6.0	MAX-6	6 / 7 / 9 / 11	√	Tapered
Ø7.0	MAX-7	7 / 9 / 11	√	Tapered
Ø8.0	MAX-8	7 / 9 / 11	√	Tapered
Ø9.0	MAX-9	7 / 9 / 11	√	Tapered

Supplied with fixture mount.

Placement Notes

A: One full turn of the implant corresponds to 0.6 mm in placement depth for EXT-HEX straight and Co-Axis® implants.
B: One full turn of the External Hex MAX implant corresponds to 0.8 mm in placement depth.

Fixture Mounted Implants

A) Surgical procedure for **connector to handpiece**.

1. Connect the **standard** connector to handpiece (I-CON-X/XS) or **universal** connector (I-CONU-X/XS), to the handpiece of the implant motor unit.
2. Engage the implant fixture mount.
3. Carefully remove the implant from the sterile vial.
4. Place the implant into the prepared osteotomy at 15-20rpm and with maximum torque set at 40-45Ncm, with slight downward pressure.
5. If maximum torque is reached by the handpiece before the implant is fully seated follow Step B) 1.1 or B) 1.2 for surgical wrench assembly instructions, and fully seat the implant manually. Alternatively, use the wrench convertor (I-WI-SH), inserted into the surgical wrench (I-TWS-B45 /B100), to engage the hex on the implant fixture mount, and fully seat the implant.

B) Surgical procedure for **connector with manual torque wrench converter,**
(This is an additional step for torqueing the implant at a higher torque, or placing the implant with the torque wrench only).

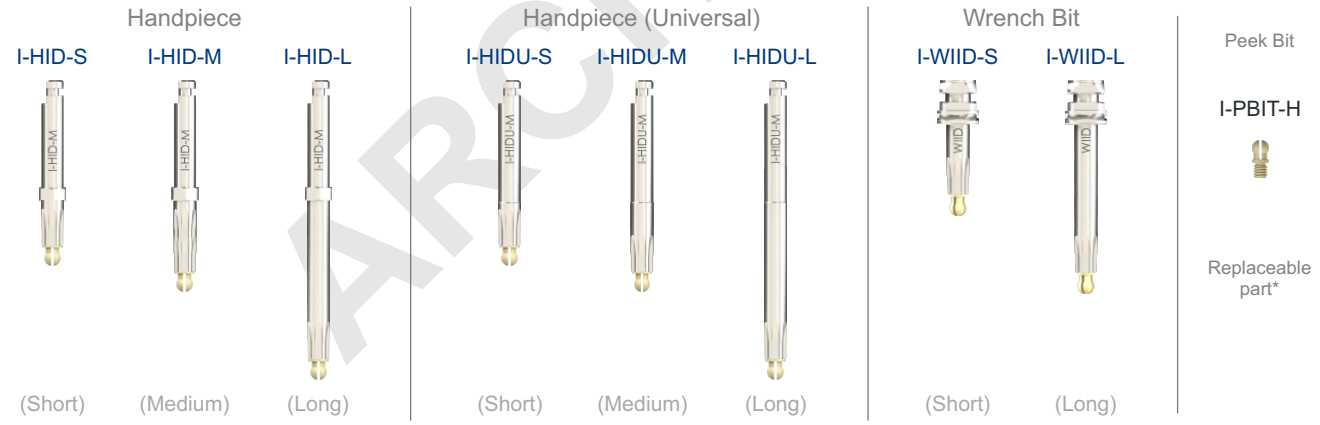
1.1 Connect the **standard** connector to handpiece (I-CON-X/ XS) to the wrench converter (I-WI-CST), and insert it into the surgical wrench (I-TWS-B45 /B100).
1.2 Connect the **universal** connector to handpiece (I-CONU-X /XS) to the wrench converter (I-WI-SL), and insert it into the surgical wrench (I-TWS-B45 /B100).
2. This assembly is used to engage the implant fixture mount.
3. Pick up and carefully remove the implant from the sterile vial.
4. Place and fully seat the implant manually into the prepared osteotomy.

External Hex internal drive implants

Implant insertion tools are used for all External Hex internal drive implants. *(Fig. 4)*

Insertion Tools

(Fig. 3)



** **Important:** The PEEK bits (I-PBIT-H) should be replaced on a regular basis. General wear & tear are to be expected with regular use. (Items sold separately)*

Compatible implants

(Fig. 4)

EXTERNAL HEX — **INTERNAL DRIVE**

	CODE	LENGTHS	Cylindrical or Tapered
Ø4.0	IBi	7 / 8.5 / 10 / 11.5 / 13 / 15 / 18/ 20	C
	IBTi	8.5 / 10 / 11.5 / 13 / 15 / 18	T
Ø5.0	BAi	7 / 8.5 / 10 / 11.5 / 13 / 15 / 18	C
	BATi	10 / 11.5 / 13 / 15 / 18	T
Ø6.0	BBBi	7 / 8.5 / 10 / 11.5 / 13 / 15	C
	BBBTi	8.5 / 10 / 11.5 / 13 / 15 / 18	T

Placement Notes
A: One full turn of the implant corresponds to 0.6 mm in placement depth for EXT-HEX straight implants.

Non-Fixture mounted Implants
A) Surgical procedure for **latch insertion tools.**

1. The standard insertion tool (I-HID-S / M/L) or the universal insertion (I-HIDU/S/M/L) tool is connected to the handpiece of the implant motor unit. *(Fig. 3)*
2. Engage the hex of the implant with the insertion tool.
3. Carefully remove the implant from the sterile vial.
4. The insertion tool must be fully engaged in the implant before torque is applied.
5. Place the implant into the prepared osteotomy at 15-20rpm with maximum torque set at 40-45Ncm, with slight downward pressure.
6. If maximum torque is reached before the implant is fully seated follow Step B).1 & B)2 for surgical wrench assembly instructions and fully seat the implant manually.

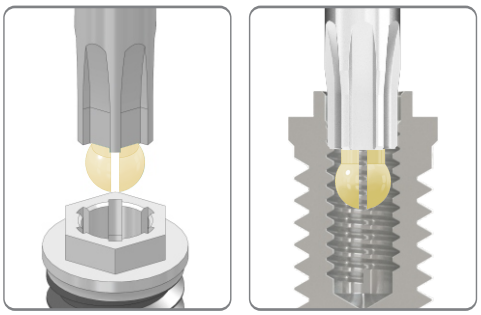
B) Surgical procedure for **latch insertion tools, used with wrench converters**, and a manual torque wrench.

1. The standard latch insertion tool (I-HID/-S/M/L) and the wrench converter (I-WI-CST) is connected, and inserted into the surgical wrench (I-TWS-B45 /B100). *(Fig. 3)*
2. The universal latch insertion tool (I-HIDU/-S/M/L) and the wrench converter (I-WI-SL) is connected, and inserted into the surgical wrench (I-TWS-B45 /B100). *(Fig. 3)*
3. These assemblies are used to engage the implants external hex internallly.
4. Pick up and carefully remove the implant from the sterile vial.
5. Place and fully seat the implant manually, into the prepared osteotomy.

Surgical procedure for **wrench insertion tools,** and a manual torque wrench.

7. The wrench insertion tool (I-WIID / S/L) and wrench converter (I-WI-SS) is connected, and inserted into the surgical wrench (I-TWS-B45 /B100). *(Fig. 3)*
8. Engage the external hex of the implant with the wrench tool.
9. Pick up and carefully remove the implant from the sterile vial.
10. Place the implant manually into the prepared osteotomy.
11. Can also be used to fully seat the implant for all indications above.

(Fig. 5)



Insertion tool insertion protocol
Align driver to engage with the spline of the implant. *(Fig. 4)*
Plastic nib (I-PBIT-H) engages internal threads to provide retention.

External Hex internal drive implants

Implant insertion tools are used for all External Hex internal drive implants. *(Fig. 7)*

Insertion Tools *(Fig. 6)*

Handpiece
I-HIDNU-M

(Medium)

Peek Bit
I-PBIT-H16

Replaceable part*

Compatible implants *(Fig. 7)*

EXTERNAL HEX **INTERNAL DRIVE**

INPi Implants are available in the following lengths:

ITEM CODE	IMPLANT LENGTHS (in mm)
INPi 8.5	8.5
INPi 10	10
INPi 11.5	11.5
INPi 13	13
INPi 15	15

** **Important:** The PEEK bits (I-PBIT-H16) should be replaced on a regular basis. General wear & tear are to be expected with regular use. (Items sold separately)*

Placement Notes

A: One full turn of the implant corresponds to 0.6 mm in placement depth for EXT-HEX straight implants.

Non-Fixture mounted Implants

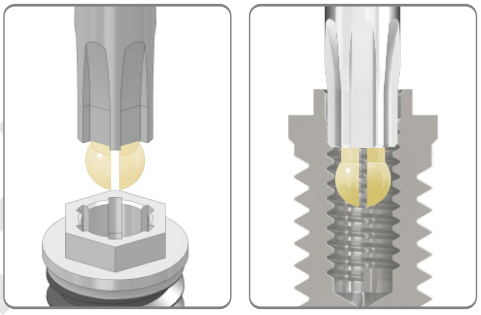
A) Surgical procedure for **latch insertion tools.**

1. The universal insertion (I-HIDNU/S/M/L) tool is connected to the handpiece of the implant motor unit. *(Fig. 6)*
2. Engage the hex of the implant with the insertion tool.
3. Carefully remove the implant from the sterile vial.
4. The insertion tool must be fully engaged in the implant before torque is applied.
5. Place the implant into the prepared osteotomy at 15-20rpm with maximum torque set at 40-45Ncm, with slight downward pressure.
6. If maximum torque is reached before the implant is fully seated follow Step B).1 for surgical wrench assembly instructions and fully seat the implant manually.

B) Surgical procedure for **latch insertion tools, used with wrench converters**, and a manual torque wrench.

1. The universal latch insertion tool (I-HIDU/-S/M/L) and the wrench converter (I-WI-SL) is connected, and inserted into the surgical wrench (I-TWS-B45 /B100). *(Fig. 6)*
2. These assemblies are used to engage the implants external hex internallly.
3. Pick up and carefully remove the implant from the sterile vial.
4. Place and fully seat the implant manually, into the prepared osteotomy.

(Fig. 8)



Insertion tool insertion protocol

Align driver to engage with the spline of the implant *(Fig. 8)*.
Plastic nib (I-PBIT-H16) engages internal threads to provide retention.

Internal Octagon Implants (IT) Implants

Implants are available with or without a pre-mounted fixture mount. *(Fig. 10)*

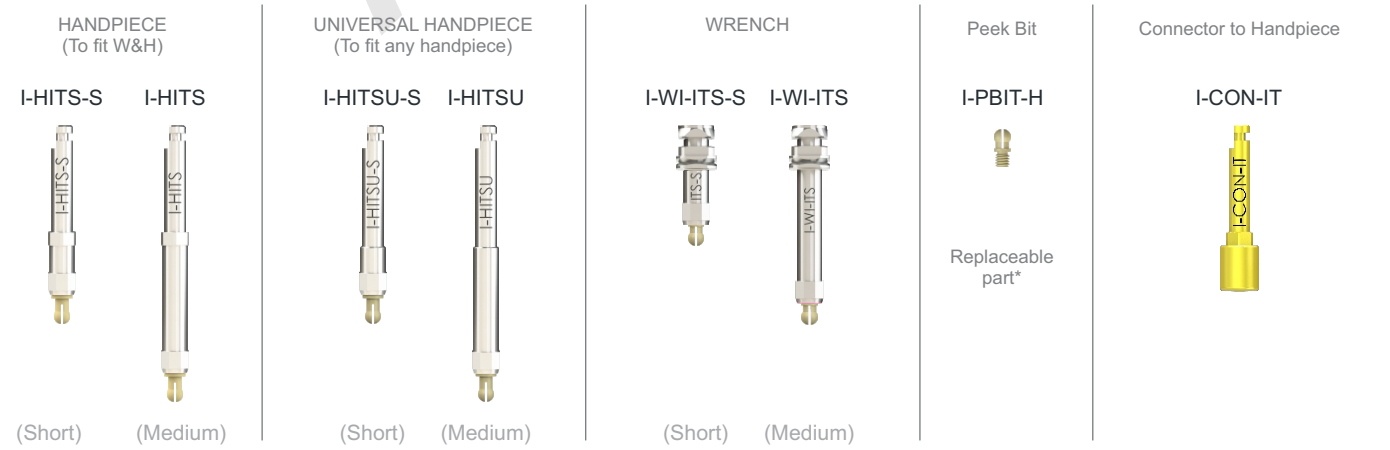
Implants with a fixture mount attached for surgical insertion, are indicated with “f” in the item code. The connecter to handpiece (I-CON-IT), is used to connect the fixture mount to the handpiece. *(Fig.9)*

Co-Axis® and MAXIT® implants are all pre-mounted by default with a fixture mount attached to the implant. The connecter to handpiece, I-CON-IT, is used. *(Fig. 9)*

For implants without a fixture mount, a handpiece implant insertion tool is needed, I-HITS. This instrument engages the internal octagon of the implant for surgical insertion. *(Fig. 9)*

Insertion Tools

(Fig. 9)



** **Important:** The PEEK bits (I-PBIT-H) should be replaced on a regular basis. General wear & tear are to be expected with regular use. (Items sold separately)*

Compatible implants

(Fig. 10)

IT (Internal Octagon) — **Straight Implants**

	CODE	LENGTHS	LENGTHS *	
Ø3.3	ITC3	6 / 8 / 10 / 12 / 14	6f / 8f / 10f / 12f / 14f	Cylindrical
Ø4.0	ITT4	8 / 10 / 12 / 14	8f / 10f / 12f / 14f	Tapered
Ø4.1	ITC4	6 / 8 / 10 / 12 / 14	6f / 8f / 10f / 12f / 14f	Cylindrical
Ø4.9	ITC5	6 / 8 / 10 / 12 / 14	6f / 8f / 10f / 12f / 14f	Cylindrical
Ø4.9*	ITC6-5	6 / 8 / 10 / 12	6f / 8f / 10f / 12f	Cylindrical
Ø5.0	ITT5	8 / 10 / 12 / 14	8f / 10f / 12f / 14f	Tapered
Ø5.0*	ITT6-5	8 / 10 / 12	8f / 10f / 12f	Tapered
Ø6.0*	ITT6	8 / 10 / 12	8f / 10f / 12f	Tapered

* Implants with (f) in code indicates with fixture mount

* Wide Interface

IT (Internal Octagon) — **Co-Axis®**

	CODE	LENGTHS	
Ø4.0	ITST12d-4xxf	8 / 10 / 12 / 14	Tapered
Ø5.0	ITST12d-5xxf	8 / 10 / 12 / 14	Tapered

Prosthetic platform angled at 12°
Supplied with fixture mount.

IT (Internal Octagon) — **MAXIT®**

	CODE	LENGTHS	
Ø7.0	MAXIT®7	7 / 9 / 11	Tapered
Ø8.0	MAXIT®8	7 / 9 / 11	Tapered
Ø9.0	MAXIT®9	7 / 9 / 11	Tapered

Supplied with fixture mount.

Placement Notes

A: One full turn of the implant corresponds to 1.0 mm in placement depth for ITC ø3 mm implants.
B: One full turn of the implant corresponds to 1.25 mm in placement depth for ITC ø4, ø5, and ø6mm implants.
C: One full turn of the implant corresponds to 0.6 mm in placement depth for ITT ø4, ø5mm / ITT6-5/ITC6-5 implants.
D: One full turn of the implant corresponds to 0.8 mm in placement depth for ITT ø6mm / MAXIT implants.

Fixture Mounted Implants

A) Surgical procedure for **connector to handpiece**.

1. Connect the **standard** connector to handpiece (I-CON-IT) to the handpiece of the implant motor unit. *(Fig. 9)*
2. Engage the implant fixture mount.
3. Carefully remove the implant from the sterile vial.
4. Place the implant into the prepared osteotomy at 15-20rpm and with maximum torque set at 40-45Ncm, with slight downward pressure.
5. If maximum torque is reached by the handpiece before the implant is fully seated follow Step B)1 for surgical wrench assembly instructions, and fully seat the implant manually.

B) Surgical procedure for **connector with manual torque wrench converter.**
(Steps for torqueing the implant at a higher torque, and additional step for placing the implant with the torque wrench only).

1. Connect the **standard** connector to handpiece (I-CON-IT) to the wrench converter (I-WI-CST), and insert it into the surgical wrench (I-TWS-B45 /B100). *(Fig. 9)*
2. This assembly is used to engage the implant fixture mount
3. Pick up and carefully remove the implant from the sterile vial.
4. Place and seat the implant manually, into the prepared osteotomy.

Non-Fixture Mounted Implants

C) Surgical procedure for **latch insertion tools.**

1. Connect the **standard** insertion tool (I-HITS/-S) or the **universal** insertion tool (I-HITSU/S) to the handpiece of the implant motor unit. *(Fig. 9)*
2. Engage the octagons of the implant with the insertion tool.
3. Carefully remove the implant from the sterile vial.
4. The insertion tool must be fully engaged in the implant before torque is applied.
   NOTE: If the octagon did not align during pick-up then the octagon will engage when implant starts to turn in the bone. The

octagon is fully engaged if the top of the octagon is flush with the top of the implant, only then can maximum tongue be applied. If they do not engage: change the direction of the rotation, rotate the implant half a turn, change the direction again, this will ensure the engagement of the octagon. *(Fig 9)*

5. Place the implant into the prepared osteotomy at 15-20rpm and with maximum torque set at 40-45Ncm, with slight downward pressure.
6. If maximum torque is reached by the handpiece before the implant is fully seated follow Step D)1.1 or D) 1.2 for surgical wrench assembly instructions and fully seat the implant.

D) Surgical procedure for **latch insertion tools, used with manual torque wrench converter.**

1.1 Connect the **standard** latch insertion tool (I-HITS/-S) and the wrench converter (I-WI-CST), and insert it into the surgical wrench (I-TWS-B45 /B100). *(Fig. 9)*

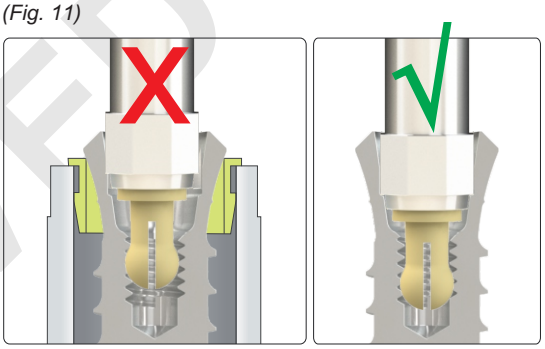
1.2 Connect the **universal** latch insertion tool (I-HITSU/-S) and the wrench converter (I-WI-SL), and insert it into the surgical wrench (I-TWS-B45 /B100).

3. These assemblies are used to engage into the implants internal octagon.
4. Pick up and carefully remove the implant from the sterile vial.
5. Place and fully seat the implant manually into the prepared osteotomy.

E) Surgical procedure for **wrench insertion tools,** and a manual torque wrench.

1. Connect the **wrench** insertion tool (I-WI-ITS / S) and wrench converter (I-WI-SS), and insert it into the surgical wrench (I-TWS-B45 /B100). *(Fig. 9)*
2. Engage the octagons of the implant with the wrench tool.
3. Pick up and carefully remove the implant from the sterile vial.
4. Place and fully seat the implant manually into the prepared osteotomy.
5. Can also be used to fully seat the implant, for all the indications above.

(Fig. 11)



Insertion tool insertion protocol

Ensure that the octagon on the insertion tool and implant engage. *(Fig. 11)*
The octagon is fully engaged if the top of the octagon is flush with the top of the implant.

DEEP CONICAL Implants

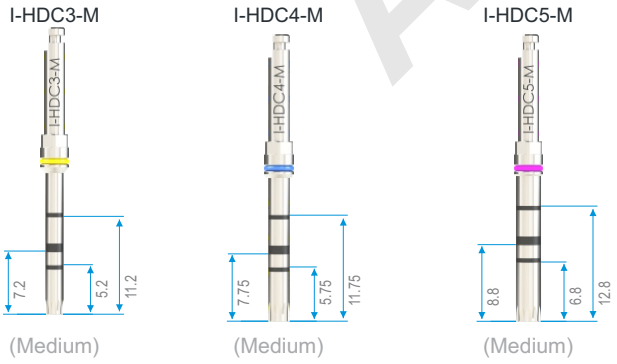
Implants are available *(Fig. 14)* without a pre-mounted fixture mount, an insertion tool is used.

Co-Axis implants are all pre-mounted by default with a fixture mount attached to the implant. The connecter to handpiece is used.

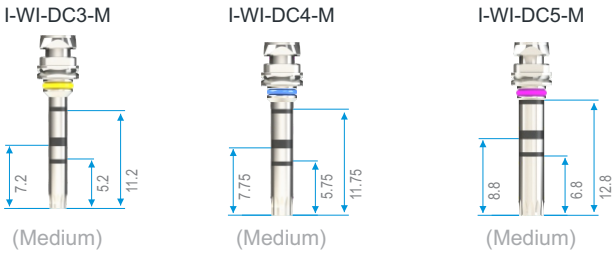
Insertion tools

(Fig. 12)

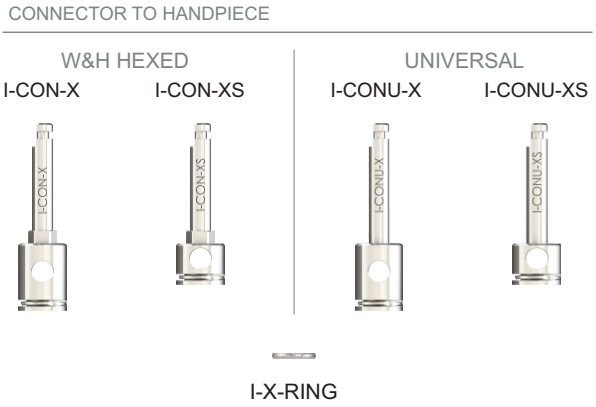
HANDPIECE (To fit W&H)



WRENCH



CONNECTOR TO HANDPIECE



Compatible implants

(Fig. 14)

DEEP CONICAL — Straight

	CODE	LENGTHS	Cylindrical or Tapered
Ø3.0	DCT30	9 / 11 / 13	T
	DCC30	8/11/ / 13 / 15	C
Ø3.5	DCT35	8 / 9 / 11 / 13 / 15	T
	DCC35	8 / 9 / 11 / 13 / 15	C
Ø4.0	DCT40	6 / 8 / 9 / 11 / 13 / 15	T
	DCC40	6 / 8 / 9 / 11 / 13 / 15	C
Ø5.0	DCT50	9 / 11 / 13 / 15	T
	DCC50	9 / 11 / 13 / 15	C

DEEP CONICAL — INVERTA®

	CODE	LENGTHS	Cylindrical or Tapered
Ø3.5 - Ø4.5	IV-DC35-45	8 / 10 / 11 / 13 / 15	T
Ø4.0 - Ø5.0	IV-DC40-50	10 / 11 / 13 / 15	T
Ø5.0 - Ø6.0	IV-DC50-60	10 / 11 / 13 / 15	T

DEEP CONICAL — Co-Axis®

	CODE	LENGTHS	Cylindrical or Tapered
Ø3.5	DCT35xx-12d	8 / 9 / 10 / 11 / 13 / 15	T
	DCC35xx-12d	8 / 9 / 10 / 11 / 13 / 15	C
Ø4.0	DCT40xx-12d	8 / 9 / 10 / 11 / 13 / 15	T
	DCC40xx-12d	8 / 9 / 10 / 11 / 13 / 15	C
Ø4.0	DCT50xx-12d	8 / 9 / 10 / 11 / 13 / 15	T
	DCC50xx-12d	8 / 9 / 10 / 11 / 13 / 15	C

* Prosthetic platform angled at 12°

DEEP CONICAL — INVERTA®

	CODE	LENGTHS	Cylindrical or Tapered
Ø3.5 - Ø4.5	IV-DC3512D-45	11 / 13 / 15	T
Ø4.0 - Ø5.0	IV-DC4012D-50	11 / 13 / 15	T

* Prosthetic platform angled at 12°

Placement Notes

A: On the fixture mount a black laser marking is visible at 3 mm above the implant platform (to indicate depth of placement). One full turn of the implant corresponds to 1 mm in placement depth for tapered DCT Co-Axis® implants, and 0.66mm for cylindrical DC Co-Axis® implants.

B: On the insertion tools are laser marked depth lines to indicate depth of implant placement. One full turn of the implant corresponds to 1 mm in placement depth for tapered DCT implants, and 0.6mm for cylindrical DCC implants.

Fixture Mounted Implants

A) Surgical procedure for **connector to handpiece**.

1. Connect the **standard** connector to handpiece (I-CON-X/XS) or **universal** connector (I-CONU-X/XS), and insert it to the handpiece of the implant motor unit. *(Fig. 13)*
2. Engage the implant fixture mount.
3. Carefully remove the implant from the sterile vial.
4. Place the implant into the prepared osteotomy at 15-20rpm and with maximum torque set at 40-45Ncm, with slight downward pressure.
5. If maximum torque is reached by the handpiece before the implant is fully seated follow Step C)1.1 or C) 1.2 for surgical wrench

assembly instructions, and fully seat the implant manually. Alternatively, use the wrench convertor (I-WI-SH), inserted into the surgical wrench (I-TWS-B45 /B100), to engage the hex on the implant fixture mount, and fully seat the implant.

B). Surgical procedure for **latch insertion tools** used with DC implants pre-mounted with a fixture mount.
1. Connect the **latch** insertion tool (I-HDCx-S / M), to the handpiece of the implant motor unit. *(Fig. 13)*
2. Insert and engage the hex in the top section of the fixture mount with the latch insertion tool. *(Fig. 14)*
3. Carefully remove the implant from the sterile vial.
4. Place the implant into the prepared osteotomy at 15-20rpm and with maximum torque set at 40-45Ncm, with slight downward pressure.
5. If maximum torque is reached by the handpiece before the implant is fully seated, remove the insertion tool from the fixture mount, follow Step C).1 & C).2 for surgical wrench assembly instructions, and fully seat the implant manually.

C). Surgical procedure for **connector with manual torque wrench converter**
(Steps for torqueing the implant at a higher torque, or placing the implant with the torque wrench only).
1.1 Connect the **standard** connector to handpiece (I-CON-X/ XS) and the wrench converter (I-WI-CST), and insert into the surgical wrench (I-TWS-B45 /B100). *(Fig. 13)*
1.2 The **universal** connector to handpiece (I-CONU-X /XS) and the wrench converter (I-WI-SL) is connected, and inserted into the surgical wrench (I-TWS-B45 /B100). *(Fig. 13)*
2. This assembly is used to engage the implant fixture mount
3. Pick up and carefully remove the implant from the sterile vial.
4. Place and seat the implant manually, into the prepared osteotomy.

Non-Fixture mounted Implants

D) Surgical procedure for **latch insertion tools.**
1. Connect the standard insertion tool (I-HDCx-S / M), and insert it into to the handpiece of the implant motor unit.
2. Engage the hex of the implant with the insertion tool. *(Fig. 13)*
3. Carefully remove the implant from the sterile vial.
4. The insertion tool must be fully engaged in the implant before torque is applied.
5. Place the implant into the prepared osteotomy at 15-20rpm and with maximum torque set at 40-45Ncm, with slight downward pressure.
6. If maximum torque is reached by the handpiece before the implant is fully seated follow Step E) 1. for surgical wrench assembly instructions and fully seat the implant manually.

E) Surgical procedure **for latch insertion tools, used with wrench converters**, and a manual torque wrench.
1. Connect the **latch** insertion tool (I-HDCx-S/ M) and the **wrench** converter (I-WI-CST), and insert it into the surgical wrench (I-TWS-B45 /B100). *(Fig. 13)*
2. This assembly is used to engage the implants internal connection.
3. Pick up and carefully remove the implant from the sterile vial.
4. Place and seat the implant manually, into the prepared osteotomy.

F) **DC wrench insertion tools** (DC implant supplied without a fixture mount).
1. Connect the **wrench** insertion tool (I-WI-DC(x)-S / M) and wrench converter (I-WI-SS), and insert it into the surgical wrench (I-TWS-B45 /B100). *(Fig. 13)*
2. Engage the internal conical connection of the implant with the wrench tool.
3. Pick up and carefully remove the implant from the sterile vial.
4. Place and seat the implant manually, into the prepared osteotomy.
5. Can also be used to fully seat the implant, for all the indications above.

Insertion tool illustrations *(Fig. 14)*

Insertion tool

Connecter to handpiece

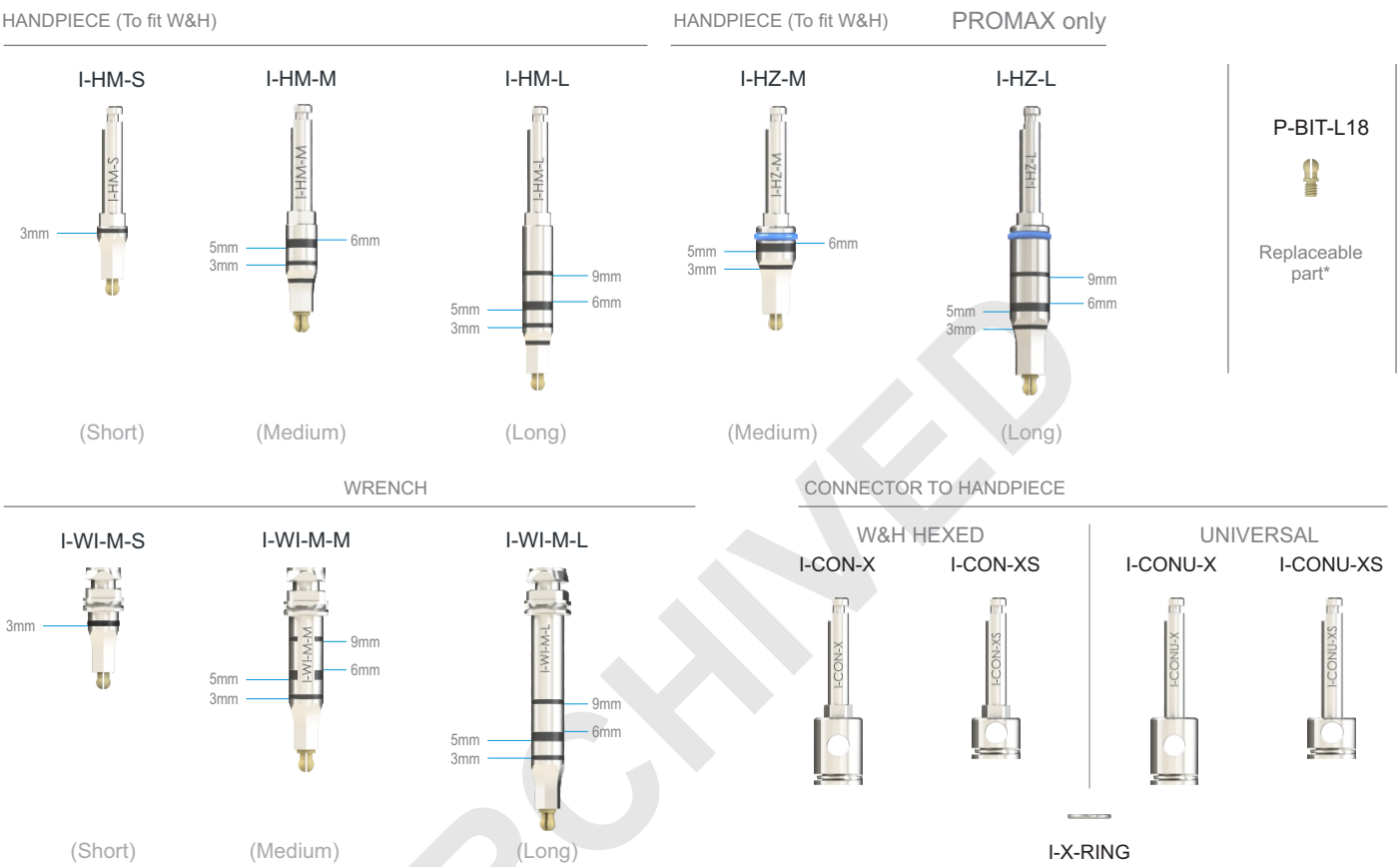
Insertion tool used with fixture mount

INTERNAL HEX Implants (PROVATA® & M-Series) — Straight

Straight and PROMAX implants *(Fig. 17)* are available without a pre-mounted fixture mount. An insertion tool is used.

Co-Axis® implants are all pre-mounted by default with a fixture mount attached to the implant. The connector to handpiece is used. Or the insertion tool is connected into the fixture mount, as insertion tool.

Insertion Tools *(Fig. 16)*



NOTE: • Laser markings at 3mm, 5mm, 6mm and/or 9mm from implant platform.

Important: *The PEEK bits (I-PBIT-L18) should be replaced on a regular basis. General wear & tear are to be expected with regular use. (Items sold separately)*

Compatible implants *(Fig. 17)*

INTERNAL HEX (PROVATA® & M-Series) — Straight

PROVATA

	CODE	LENGTHS	MSc	Cylindrical or Tapered
Ø3.0	PRO3	8 / 10 / 11 / 13 / 15 / 18	√	T
Ø4.0	PRO4	6 /8 / 10 / 11 / 13 / 15 / 18	√	T
Ø5.0	PRO5	8 / 10 / 11 / 13 / 15 / 18	√	T

M-SERIES

	CODE	LENGTHS	Cylindrical or Tapered
Ø3.7	IM-T37	8 / 10 / 11 / 13 / 15	T
Ø4.2	IM-T42	8 / 10 / 11 / 13 / 15 / 18	T
Ø5.0	IM-T50	8 / 10 / 11 / 13 / 15	T

INTERNAL HEX (PROVATA® & M-Series) — Co-Axis®

* Prosthetic platform angled at 12°

PROVATA

	CODE	LENGTHS	MSc	Cylindrical or Tapered
Ø4.0	PRO12D4	8 / 10 / 11 / 13 / 15 / 18	√	T
Ø5.0	PRO12D5	8 / 10 / 11 / 13 / 15 / 18	√	T

M-SERIES

	CODE	LENGTHS	Cylindrical or Tapered
Ø4.2	IM-T42xx-12d	8 / 10 / 11 / 13 / 15 / 18	T

PROMAX MAX

	CODE	LENGTHS	MSc	Cylindrical or Tapered
Ø6.0	PROMAX6	7 / 9 / 11	√	T
Ø7.0	PROMAX7	7 / 9 / 11	√	T
Ø8.0	PROMAX8	7 / 9 / 11	√	T
Ø9.0	PROMAX9	7 / 9 / 11	√	T

Placement Notes

PROVATA

A: On the fixture mount black laser markings are visible at 3, 5, 6, and 9 mm above the implant platform to indicate depth of placement. One full turn of the implant corresponds to 0.6 mm in placement depth for Provata Co-Axis® implants. A dimple on the fixture mount assists the user in obtaining the correct rotational alignment of the implant. The dimple is located above the highest point of the angulated platform.

B: On the insertion tools black laser markings, are visible *(Fig. 15)* to indicate depth of placement. One full turn of the implant corresponds to 0.6 mm in placement depth for Provata straight implants.

C: On the insertion tools black laser markings, are visible *(Fig. 15)* to indicate depth of placement. One full turn of the PROMAX implant corresponds to 0.8 mm in placement depth.

M-Series

D: On the fixture mount black laser markings are visible at 3, 5, 6, and 9 mm above the implant platform to indicate depth of placement. One full turn of the implant corresponds to 1 mm in placement depth for M-Series Co-Axis™ implants. A dimple on the fixture mount assists the user in obtaining the correct rotational alignment of the implant. The dimple is located above the highest point of the angulated platform.

E: On the insertion tools black laser markings, are visible *(Fig. 15)*) to indicate depth of placement. One full turn of the implant corresponds to 2 mm in placement depth for M-Series straight implants.

Fixture Mounted Implants

A) Surgical procedure for **connector to handpiece**.

1. Connect the **standard** connector to handpiece (I-CON-X/XS) or **universal** connector (I-CONU-X/XS), and connect it to the handpiece of the implant motor unit. *(Fig. 16)*
2. Engage the implant fixture mount.
3. Carefully remove the implant from the sterile vial.
4. Place the implant into the prepared osteotomy at 15-20rpm and with maximum torque set at 40-45Ncm, with slight downward pressure.
5. If maximum torque is reached by the handpiece before the implant is fully seated follow Step C).1 & C).2 for surgical wrench assembly instructions, and fully seat the implant manually. Alternatively, use the wrench convertor (I-WI-SH), inserted into the surgical wrench (I-TWS-B45 /B100), to engage the hex on the implant fixture mount, and fully seat the implant.

B) Surgical procedure for **latch insertion tools** used with Provata and Internal Hex implants pre-mounted with a fixture mount.

1. Connect the **latch** insertion tool (I-HM-S/M/L and I-HZ-S/M/L), to the handpiece of the implant motor unit. *(Fig. 16)*
2. Insert and engage the hex in the top section of the fixture mount with the insertion tool. The hexagon of the insertion tool in the fixture mount must fully engage before torque is applied, to prevent damage to the insertion tool/fixture mount or handpiece. The hexagon is fully engaged when the straight portion of the hexagon tool is almost completely sunken in the fixture mount.
3. Carefully remove the implant from the sterile vial.
4. Place the implant into the prepared osteotomy at 15-20rpm and with maximum torque set at 40-45Ncm, with slight downward pressure.
5. If maximum torque is reached by the handpiece before the implant is fully seated. Remove the insertion tool from the fixture mount, follow Step C) 1.1 or C) 1.2 for surgical wrench assembly instructions, and fully seat the implant manually.

C) Surgical procedure for **connector with manual torque wrench**

(Steps for torqueing the implant at a higher torque, or placing the implant with the torque wrench only).

1.1 Connect the **standard** connector to handpiece (I-CON-X/ XS) and the wrench connector (I-WI-CST), and insert it into the surgical wrench (I-TWS-B45 /B100). *(Fig. 16)*

1.2 Connect the **universal** connector to handpiece (I-CONU-X /XS) and the wrench connector (I-WI-SL), and insert it into the surgical wrench (I-TWS-B45 /B100). *(Fig. 16)*

2. This assembly is used to engage the implant fixture mount
3. Pick up and carefully remove the implant from the sterile vial.
4. Place and seat the implant manually, into the prepared osteotomy.

Non-Fixture mounted Implants

D) Surgical procedure for **latch insertion tools.**

1. Connect the **latch** insertion tool (I-HM-S/M/L and I-HZ-S/M/L), and insert it into the handpiece of the implant motor unit. *(Fig. 16)*
2. Engage the hex of the implant with the insertion tool.
3. Carefully remove the implant from the sterile vial.
4. The insertion tool must be fully engaged in the implant before torque is applied.
5. Place the implant into the prepared osteotomy at 15-20rpm and with maximum torque set at 40-45Ncm, with slight downward pressure.
6. If maximum torque is reached by the handpiece before the implant is fully seated follow Step E).1 & E)2 for surgical wrench assembly/instructions and fully seat the implant manually.

E) Surgical procedure **for latch insertion tools, used with wrench converters**, and a manual torque wrench.

1. Connect the **latch** insertion tool (I-HM-S/M/L and I-HZ-S/M/L) and the **wrench converter** (I-WI-CST), and insert it into the surgical wrench (I-TWS-B45 /B100). *(Fig. 16)*
2. These assemblies are used to engage the implants internal connection.
3. Pick up and carefully remove the implant from the sterile vial.
4. Place and seat the implant manually, into the prepared osteotomy.

F) Surgical procedure for **wrench insertion** tools and a manual torque wrench.

1. Connect the **wrench** insertion tool (I-WI-M-S/M/L) and **wrench converter** (I-WI-SS), and insert it into the surgical wrench (I-TWS-B45 /B100). *(Fig. 16)*
2. Engage the internal hexagon of the implant with the wrench tool.
3. Pick up and carefully remove the implant from the sterile vial.
4. Place the implant manually into the prepared osteotomy.
5. Can also be used to fully seat the implant, for all indications above.

Insertion tool insertion protocol

The PROVATA® Co-Axis® implants can also be placed with a special insertion tool, **without** the Fixture Mount.

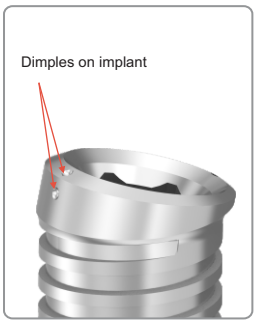
Connect the Insertion Tool (I-H-PRO12D-S / M / L) to the handpiece. *(Fig. 18-20)* Identify the dimples on the implant platform *(Fig. 18)*. This side lines up with the groove on insertion tool. Identify the groove on the tool *(Fig. 19)*. Line up the groove on the insertion tool with the dimples on the implant *(Fig. 20)*. Push the tool into the implant until the insertion tool fits flush with the implant.

Insert the implant at 15-20 rpm while applying downward pressure.

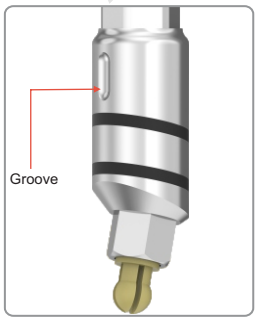
Insertion tool removal protocol

1. To remove the insertion tool from the implant, pull the insertion tool in the direction perpindicular to restorative platform and parallel to prosthetic axis *(Fig. 21)*.
2. The insertion tool will be removed in the direction of the pulling force *(Fig. 22)*.

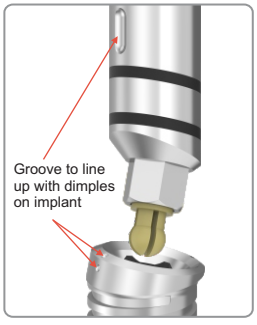
(Fig. 18)



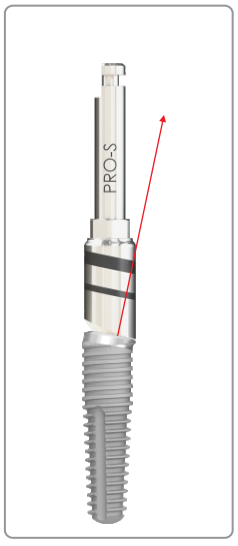
(Fig. 19)



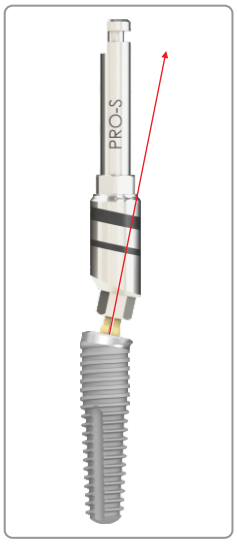
(Fig. 20)



(Fig. 21)



(Fig. 22)



NOTE: Do not detach insertion tool from implant before final placement is confirmed after initial X-rays were taken. Detach insertion tool from the handpiece only.

TRI-NEX Implants

Implant interface diameter specific, handpiece implant placement instrument is used for all TRI-NEX implants. *(Fig. 24)*

Insertion Tools

(Fig. 23)

HANDPIECE (To fit W&H) | UNIVERSAL HANDPIECE (To fit any handpiece) | Peek Bit | WRENCH

STRAIGHT IMPLANTS

Ø3.5

I-HLH-35S	I-HLH-35M	I-HLHU-35S	I-HLHU-35M	I-PBIT-L18	I-WI-LH35S	I-WI-LH35M
				 Use with Ø3.5 Placement Tools Replaceable part*		
(Short)	(Medium)	(Short)	(Medium)		(Short)	(Medium)

Ø4.3

I-HLH-43S	I-HLH-43M	I-HLHU-43S	I-HLHU-43M	I-PBIT-L2	I-WI-LH43S	I-WI-LH43M
				 Use with Ø4.3, Ø5.0 & Ø6.0 Placement Tools Replaceable part*		
(Short)	(Medium)	(Short)	(Medium)		(Short)	(Medium)

Ø5.0

I-HLH-50S	I-HLH-50M	I-HLHU-50S	I-HLHU-50M	I-PBIT-L2	I-WI-LH50S	I-WI-LH50M
				 Use with Ø4.3, Ø5.0 & Ø6.0 Placement Tools Replaceable part*		
(Short)	(Medium)	(Short)	(Medium)		(Short)	(Medium)

Ø6.0

I-HLH-60S	I-HLH-60M	I-HLHU-60S	I-HLHU-60M	I-PBIT-L2	I-WI-LH60
				 Use with Ø4.3, Ø5.0 & Ø6.0 Placement Tools Replaceable part*	
(Short)	(Medium)	(Short)	(Medium)		(Short)

Interface Specific Insertion Tools

CO-AXIS IMPLANTS

	HANDPIECE (To fit W&H)	WRENCH	Peek Bit
Ø4.3	I-L43-12d 	I-WIL-43-12d 	I-PBIT-L18  Use with Ø4.3 & Ø5.0 Placement Tools Replaceable part*
Ø5.0	I-L50-12d 	I-WIL-50-12d 	I-PBIT-L2  Use with Ø4.3 & Ø5.0 Placement Tools Replaceable part*

**Important:* *The PEEK bits (I-PBIT-L18/L2) should be replaced on a regular basis. General wear & tear are to be expected with regular use. (Items sold separately)*

Compatible implants

(Fig. 24)

TRI-NEX Implants

	CODE	LENGTHS	Cylindrical or Tapered
Ø3.5	IA-LH-35	8 / 10 / 11.5 / 13 / 16	T
	IA-LHS-35	8 / 10 / 11.5 / 13 / 15	C
Ø4.3	IA-LH-43	8 / 10 / 11.5 / 13 / 16	T
	IA-LHS-43	8 / 10 / 11.5 / 13 / 15	C
Ø5.0	IA-LH-50	8 / 10 / 11.5 / 13 / 16	T
	IA-LHS-50	8 / 10 / 11.5 / 13 / 15	C
Ø6.0	IA-LH-60	8 / 10 / 11.5 / 13 / 16	T

TRI-NEX Implants Co-Axis®

	CODE	LENGTHS	Cylindrical or Tapered
Ø4.3	IA43-12d	10 / 11.5 / 13 / 16	T
Ø5.0	IA50-12d	10 / 11.5 / 13 / 16	T

* Prosthetic platform angled at 12°

TRI-MAX

	CODE	LENGTHS	Cylindrical or Tapered
Ø7.0	TRI-MAX-7	7 / 9 / 11	T
Ø8.0	TRI-MAX-8	7 / 9 / 11	T
Ø9.0	TRI-MAX-9	7 / 9 / 11	T

Placement Notes

A: Dimple on the Co-Axis® insertion tool, assists the user in obtaining the correct rotational alignment of the implant, by lining them up with the dimples on the implant.
B: One full turn of the implant corresponds to 0.6 mm in placement depth for TRI-NEX straight and Co-Axis® implants.
C: One full turn of the TRI-MAX implant corresponds to 0.8 mm in placement depth.

A) Surgical procedure for **latch insertion tools.** (TRI-NEX implant supplied without a fixture mount).

1. Connect the **standard** insertion tool (I-HLH-XX-S/M/L) or the **universal** insertion (I-HLHU-XX/S/M/L) tool to the handpiece of the implant motor unit. *(Fig. 23)*
2. Engage the tri-lobes of the implant with the insertion tool.
3. Carefully remove the implant from the sterile vial.
4. The insertion tool must be fully engaged in the implant before torque is applied. The dimples of the insertion tool and the lobes of the implant should line up. This allows alignment of a lobe buccally.
5. Place the implant at 15-20rpm/ maximum torque set at 40-45Ncm, into the prepared osteotomy.
6. If maximum torque is reached by the handpiece before the implant is fully seated follow Step B)1.2 or B) 1.2 for surgical wrench assembly instructions and fully seat the implant manually.

B) Surgical procedure for **latch insertion tools, used with wrench converters**, and a manual torque wrench.

1.1 Connect the **standard** latch insertion tool (I-HLH-XXS/M/L) and the **wrench converter** (I-WI-CST), and insert it into the surgical wrench (I-TWS-B45 /B100). *(Fig. 23)*
1.2 The **universal** latch insertion tool (I-HLHU-xx-S/M/L-) and the wrench converter (I-WI-SL) is connected, and insert it into the surgical wrench (I-TWS-B45 /B100). *(Fig. 23)*
2. These assemblies are used to engage the implants' tri-lobes.
3. Pick up and carefully remove the implant from the sterile vial.
4. Place the implant manually, into the prepared osteotomy.

Surgical procedure for **wrench insertion tools,** and a manual torque wrench.

1. Connect the **wrench** insertion tool (I-WI-LHxx-S/M) and **wrench converter** (I-WI-SS), and insert it in the surgical wrench (I-TWS-B45 /B100). *(Fig. 23)*
2. Engage the tri-lobes of the implant with the wrench tool.
3. Pick up and carefully remove the implant from the sterile vial.
4. Place the implant manually into the prepared osteotomy.
5. Can also be used to fully seat the implant, for all indications above.

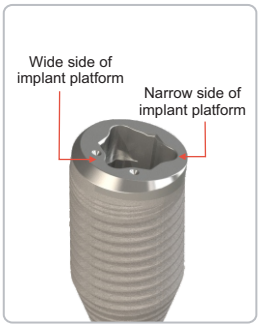
Insertion tool insertion protocol

1. Identify the two dimples on the implant platform. This side lines up with one of the lobes. *(Fig. 25)*
2. Identify the dimples on the tool *(Fig. 26)*.
3. Line up the dimples on the insertion tool with the dimples on the implant *(Fig. 27)*.
   Push the tool into the implant until the insertion tool fits flush with the implant.

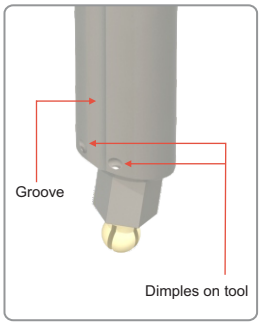
Insertion tool removal protocol

1. To remove the insertion tool from the implant, pull the insertion tool in the direction perpindicular to restorative platform and parallel to prosthetic axis *(Fig. 28)*.
2. The insertion tool will be removed in the direction of the pulling force *(Fig. 29)*.

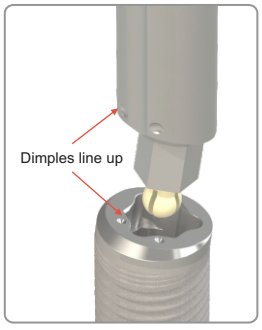
(Fig. 25)



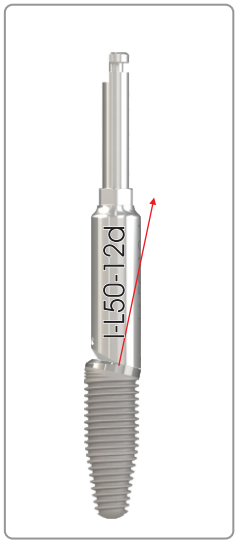
(Fig. 26)



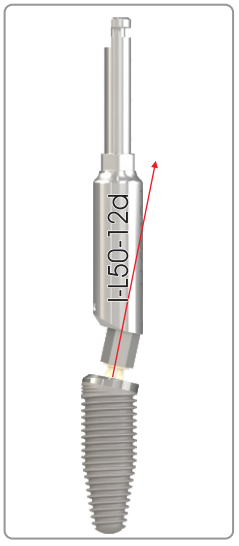
(Fig. 27)



(Fig. 28)



(Fig. 29)

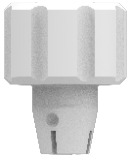


NOTE: Do not detach insertion tool from implant before final placement is confirmed after initial X-rays were taken. Detach insertion tool from the hand piece only.

ILZ Implants

ILZ Mini implants are available and pre-mounted *(Fig. 31)* with a custom made PEEK cap. *(Fig. 32)*

Insertion Tools *(Fig. 30)*

Peek cap	Wrench Insert	Handpiece Insert
		
(supplied attached on implant)	**I-WI-ILZ-S**	**I-HILZ-S/M/L**

Compatible implants *(Fig. 31)*

ILZ Implants

ITEM CODE	IMPLANT LENGTHS *(in mm)*
ILZ8.5	8.5
ILZ10	10
ILZ13	13

ITEM CODE	IMPLANT LENGTHS *(in mm)*
ILZ12d-510	10
ILZ12d-513	13

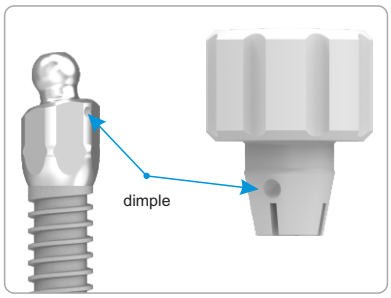
ITEM CODE	IMPLANT LENGTHS *(in mm)*
ILZ12d-310	10
ILZ12d-313	13

A) The ILZ implant is packaged with a PEEK cap which is used to carry the implant to the prepared site. The initial insertion of the implant is done by hand, using the PEEK cap.

When used with the Co-Axis® ILZ implant, a dimple on the PEEK cap indicates the position from which the ball is angled away *(Fig. 32)*. When used in the upper jaw, this dimple must be facing buccal, and facing lingual in the lower jaw.

Note: Allow the implant collar to be inserted level with, or slightly submerged in surrounding marginal bone.

(Fig. 32)



B) Surgical procedure for **latch insertion tools.**
1. Connect the **standard** insertion tool (I-HILZ-S / M / L) to the handpiece of the implant motor unit. *(Fig. 30)*
2. Engage the hexagonal of the implant with the insertion tool.
3. Carefully remove the implant from the sterile vial.
4. The insertion tool must be fully engaged on the implant before torque is applied.
5. If maximum torque is reached by the handpiece before the implant is fully seated follow Step C)1 for surgical wrench assembly instructions and fully seat the implant.

C) Surgical procedure for **latch insertion tools, used with manual torque wrench converter.**
1. Connect the **standard** latch insertion tool (I-HILZ-S / M / L) and the wrench converter (I-WI-CST), and insert it into the surgical wrench (I-TWS-B45 /B100). *(Fig. 30)*
2. These assemblies are used to engage into the implants internal octagon.
3. Pick up and carefully remove the implant from the sterile vial.
4. Place and fully seat the implant manually into the prepared osteotomy.

D) Surgical procedure for **wrench insertion tools,** and a manual torque wrench.
Final insertion to the required torque is done with a torque wrench fitted with a wrench insert, (I-WI-ILZ-S), or with a handpiece fitted with a handpiece insert, (I-HILZ-S/M/L). *(Fig. 30)* The I-HILZ also has a dimple to assist with Co-Axis orientation (maximum speed of 15rpm).
A minimum of 35Ncm insertion torque must be achieved to consider immediate loading.

Storage, cleaning & sterilisation
These devices are reusable and supplied non-sterile. If packaging is damaged do not use the product and contact your Southern representative/ or return to Southern Implants. The devises must be stored in a dry place at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics.

Reusable devices
Prior to reusing this device, it needs to be inspected, if there are signs of visible corrosion, deformed or twisted connections, dull cutting edges, expected wear and damage, this device shall be exposed of. After inspection, and reuse seems fit, the devices are cleaned, disinfected and sterilised.

General warning: Do not reuse implants, cover screws, temporary abutments, abutments and single use devises. Reusing these components may result in:
- Damage on the surface or critical dimensions, which may result in performance and compatibility degradation.
- Adds the risk of cross-patient infection and contamination if single-use items are reused.

Southern Implants does not accept any responsibility for complications associated with reused components.

If re-use seems fit:
- Containment: As soon as practically possible, remove all visible residue after use (bone, blood or tissue), by immersing the instrument in cold water (Dried soil is difficult to remove).
- Pre-Cleaning: Rinse with lukewarm water for 3 minutes, and remove hardened debris with a soft nylon brush. Avoid mechanical damage during cleaning.
- Manual Cleaning or Automated Cleaning: Prepare an ultrasonic bath with suitable detergent, sonicate for 20 minutes (Alternative methods can be used if proven by the end user). Rinse with purified / sterile water. Load devices into a thermo-disinfector. Run the cleaning and disinfection cycle, followed by the drying cycle.

NOTE: Always follow the instructions for use of the manufacturers of cleaning agents and disinfectants.

- Drying: Dry the instruments with filtered compressed air or single use lint free wipes. Pack the instruments as quickly as possible after removal into the storage container. If additional drying is necessary, dry in a clean location. Moisture on bone mills can cause corrosion and deterioration of the cutting edges.
- Inspection: Do a visual inspection of the items to check for any damage.
- Packaging: Use the correct packaging material as indicated for steam sterilisation to ensure sterility is maintained. Double packaging is recommended.

Sterilisation
Southern Implants recommends the following procedure to sterilise the instruments prior to use/re-use:

Methods to sterilise the surgical instruments:
1. Pre-vacuum Sterilisation method: Steam sterilise the instruments at 132°C (270°F) at 180-220kPa for 4 minutes. Dry for at least 20 minutes in the chamber. Only an approved wrap or pouch for steam sterilisation must be used.
2. Pre-vacuum sterilisation method: Wrapped, steam sterilise at 135°C (275°F) for 3 minutes. Dry for 20 minutes in the chamber. Use a wrap or pouch that is cleared for the indicated steam sterilisation cycle.
Note: Users in the USA must ensure that the steriliser, wrap or pouch, and all steriliser accessories are cleared by the FDA, for the intended sterilisation cycle.

Before Surgery
All components, instruments and tooling used during the clinical or laboratory procedure must be maintained in good condition and care must be taken that instrumentation does not damage implants or other components.

Clinical benefits
Patients can expect to have their missing teeth replaced and/ or crowns restored.

Healing
The healing time required for osseointegration depends on the individual and treatment protocol. It is the responsibility of the practitioner to decide when the implant can be restored. Good primary stability will govern if immediate loading can be done.

Implant care and maintenance
Potential implant patients should establish an adequate oral hygiene regime prior to Implant therapy. Proper post-operative, oral hygiene and implant maintenance instructions must be discussed with the patient, as this will determine the longevity and health of the Implants. The patient should maintain regular prophylaxis and evaluation appointments.

Materials
Handpiece “latch “drivers: Stainless Steel
Hand held drivers: Stainless Steel (Shaft) Idler: Radel
Wrench drivers: Stainless steel

Side effects
Potential Side Effects and Temporary symptoms: Pain, swelling, phonetic difficulties, gingival inflammation.
More persistent symptoms: The risks and complications with implants include, but are not limited to: (1) allergic reaction(s) to implant and/or abutment material; (2) breakage of the implant and/or abutment; (3) loosening of the abutment screw and/or retaining screw; (4) infection requiring revision of the dental implant; (5) nerve damage that could cause permanent weakness, numbness, or pain; (6) histologic responses possibly involving macrophages and/or fibroblasts; (7) formation of fat emboli; (8) loosening of the implant requiring revision surgery; (9) perforation of the maxillary sinus; (10) perforation of the labial and lingual plates; and (11) bone loss possibly resulting in revision or removal.

Breakage
Implant and abutment fractures can occur when applied loads exceed the normal functional torque strength of the material. Potential overloading conditions may result from; deficiencies in implant numbers, lengths and/or diameters to adequately support a restoration, excessive cantilever length, incomplete abutment seating, abutment angles greater than 30 degrees, occlusal interferences causing excessive lateral forces, patient parafunction (e.g., bruxing, clenching), loss or changes in dentition or functionality, inadequate prosthesis fit, and physical trauma. Additional treatment may be necessary when any of the above conditions are present to reduce the possibility of hardware complications or failure.

Changes in performance

It is the responsibility of the clinician to instruct the patient on all appropriate contraindications, side effects, and precautions as well as the need to seek the services of a trained dental professional if there are any changes in the performance of the implant (e.g., looseness of the prosthesis, infection or exudate around the implant, pain, or any other unusual symptoms that the patient has not been told to expect).

Disposal

Disposal of the device and its packaging; Follow local regulations and environmental requirements, taking different contamination levels into account. When disposing of spent items, take care of sharp drills and instruments. Sufficient PPE must be used at all times.

Disclaimer of liability

This product is part of the Southern Implants product range and should only be used with the associated original products and according to the recommendations as in the individual product catalogues. The user of this product has to study the development of the Southern Implants product range and take full responsibility for the correct indications and use of this product. Southern Implants does not assume liability for damage due to incorrect use. Please note that some Southern Implants products may not be cleared or released for sale in all markets.

Notice regarding serious incidents

Any serious incident that has occurred in relation with the device must be reported to the manufacturer of the device and the competent authority in the member state in which the user and / or patient is established.

The contact information for the manufacturer of this device to report a serious incident is as follows:

sicomplaints@southernimplants.com

Basic UDI

Product	Basic-UDI Number
Basic-UDI for Reusable Instruments	600954403876

Related literature & catalogues

CAT-2004 - Tri-Nex Implants Product Catalogue
CAT-2005 - IT Implants Product Catalogue
CAT-2010 - Osseointegrated Fixtures Catalogue
CAT-2020 - External Hex Implants Product Catalogue
CAT-2042 - Deep Conical Implants Product Catalogue
CAT-2043 - Internal Hex Implants Product Catalogue
CAT-2060 - PROVATA® Implants Product Catalogue
CAT-2069 - INVERTA® Implants Product Catalogue
CAT-2070 - Zygomatic Implants Product Catalogue
CAT-2087M- ILZ Mini Implants Product Catalogue

Symbols and Warnings

Manufacturer: Southern Implants
1 Albert Rd, P.O Box 605 IRENE, 0062,
South Africa.
Tel: +27 12 667 1046

CE 2797 | Rx ONLY Prescription device* | STERILE R Sterilization using Irradiation | NON STERILE Non-sterile | Caution | Consult instruction for use | Use by date (mm-yy) | 2 Do not reuse | 2 STERILIZE Do not re-sterilize | LOT Batch code | Do not use if package is damaged | MD Medical Device

* Prescription device: Rx only. Caution: Federal Law restricts this device to sale by or on the order of a licenced physician or dentist.

Canada licence exemption: Please note that not all products may have been licensed in accordance with Canadian law.