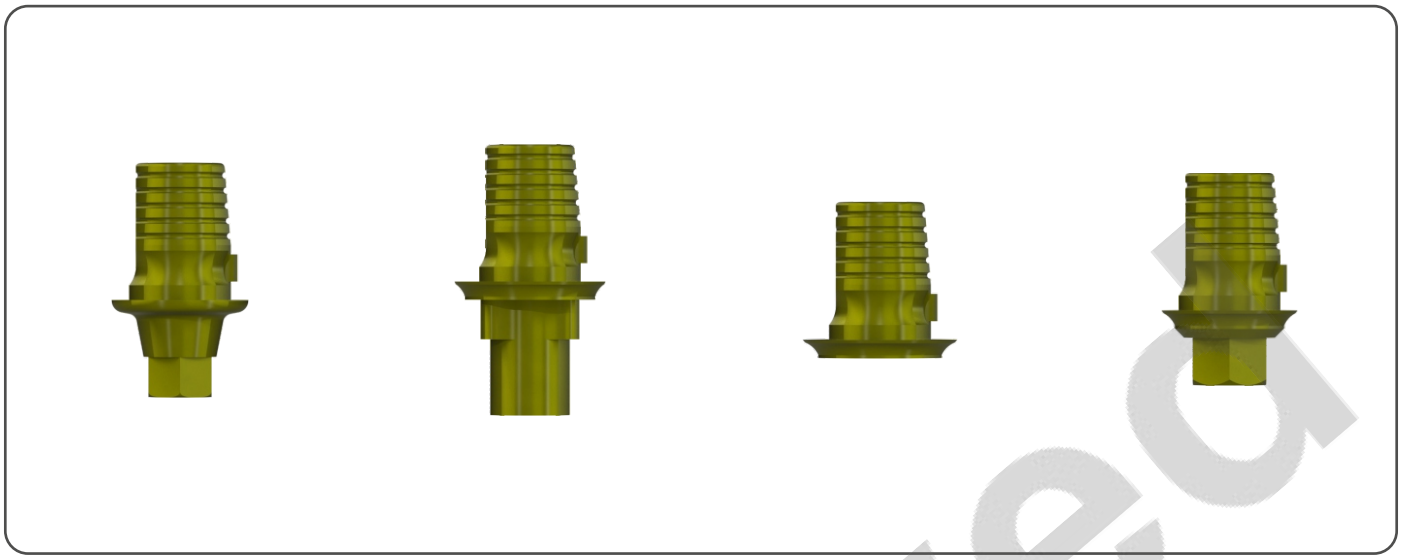
SOUTHERNIMPLANTS

INSTRUCTIONS FOR USE:
TIB Abutments



Intended use:

Southern Implants dental abutments are intended to be used in the Maxilla or Mandible for supporting a prosthesis on endosseous implants in order to restore chewing function for the patient.

Description:

TIB abutments are pre-manufactured components that are connected direct to an endosseous implant for use as an aid in prosthetic rehabilitation. The TIB abutment is made from titanium or titanium alloy (Ti-6AL-4V) and anodised gold. TIB abutments are only available in engaging.

Note: Screws are sold separately for all abutments.

The TIB abutments are available for the Internal Hex, Deep Conical, Tri-Nex, External Hex and Provata interfaces. Refer to individual product catalogues for product characteristics and compatible accessories:
M-Series (CAT-2043), DC (CAT-2042), Tri-Nex (CAT-2004), Provata (CAT-2060), External Hex (CAT-2020).

Table 1

Product range	Product code	Platform ø of product intended to be used with	Southern Scan flag	3rd party scan body	Engaging	Final torque	Abutment screw
External hex range	TIB-EX-34	ø3.4mm external hex implants	SF-EX-34	Scan body L	√	32-40Ncm	TSHZ3 (3 Series Screws Refer to catalogue for codes & instrument detail)
	TIB-EX-40	ø4mm external hex implants	SF-EX-40	Scan body L	√		
	TIB-EX-50	ø5mm external hex implants	SF-EX-50	Scan body L	√		
	TIB-EX-60	ø6mm external hex implants	SF-EX-60	Scan body L	√		
Tri-nex range	TIB-EL-35	ø3.5mm tri-nex implants	SF-EL-35	Scan body L	√	32-40Ncm	TS-L-18
	TIB-EL-43	ø4.3mm tri-nex implants	SF-EL-43	Scan body L	√	32-40Ncm	TS-L-20
	TIB-EL-50	ø5mm tri-nex implants	SF-EL-50	Scan body L	√		
	TIB-EL-60	ø6mm tri-nex implants	SF-EL-60	Scan body L	√		
DC, Deep conical range	TIB-DC4	ø4mm deep conical implants	SF-DC4	Scan body L	√	20Ncm	TS-DC4-16
	TIB-DC5	ø5mm deep conical implants	SF-DC5	Scan body L	√	25-32Ncm	TS-DC5-20
M-series & Provata internal hex range	TIB-M	ø3.75, ø4.20 & ø5mm internal hex implants & ø6.00mm PROMAX	SF-M	Scan body L	√	32Ncm	TS-Z-18
	TIB-Z	ø7.00, ø8.00 &9.00mm PROMAX	SF-Z	Scan body L	√		

Note: refer to product catalogue for instruments and screw types available.

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Images are for illustration purposes only and do not necessarily accurately represent the product.

Indications for use:

TIB abutments engaging are indicated for single unit screw retained restorations direct to an endosseous implant with the crown cemented onto the engaging TIB, during CADCAM procedures. A screw retained restoration is indicated when the screw access hole is located through the cingulum of anterior teeth and occlusal surface of posterior teeth.
If the position of the screw access holes are not favourable, custom abutments can be milled and cemented to the TIB abutment, and screwed onto the endosseos implant with the final restoration cemented onto it.

Contraindications:

Do not use in patients:
- who are medically unfit for dental implant procedures.
- who are allergic or have hypersensitivity to pure titanium or titanium alloy (Ti-6AL-4V).
- where adequate numbers of implants could not be placed to achieve full functional support for a prosthesis.

Warnings:

- **These instructions are not intended as a substitute for adequate training.**
- For the safe and effective use of dental implants it is strongly 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.

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 who 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, periodontal status, and adequacy of bone.
- 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 procedure:

- Care must be taken that parts are not swallowed during any of the procedures, thus rubber-dam application is recommended when appropriate.
- Care must be taken to apply the correct tightening torque of abutments and abutment screws.

Post-procedure:

- Regular patient follow-up, and proper oral hygiene must be achieved are essential for favourable long-term results.

Digital workflow by using digital libraries:

Scanning procedure:

1. Download Southern Implants digital library for 3Shape and Exocad by registering on www.southernimplants.com.
   Note: refer to the website on a regular basis for library updates.
2. Load the libraries into the CADCAM system by following their instructions.
3. The implant position is obtained digitally by an intraoral scan of the patient with Scan flags attached to the endosseous implant, or a desktop scan of the dental model with the Scan flags attached to the laboratory analogue.
4. Remove the Scan flag from the implants or from the model, replace healing abutments.
5. The scan is then imported into the design software.

Designing procedures:

6. The Scan flag in the digital form is now matched and aligned with the corresponding Scan flag in the library.
7. The software recognise the relative position of the Scan flag to the implant or analogue, and to place the abutment for the design steps.
8. The TIB abutment/s are chosen from the library, the user will determine the desired tooth or teeth positions needed for the abutment/s, and the path of insertion will be determined. This will govern if a screw retained or cemented restoration is possible.
9. The software will guide the user through the steps to complete the restoration.
10. Selection of the restorative material: (the most common material to use is Zirconia.)

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Milling & sintering procedures:

11. The milled custom abutment or screw retained restoration is to be sintered to the specifications of the manufacturer if Zirconia was used. Once sintered the abutment, custom abutment is cemented to the prefabricated titanium TIB abutment by closing the screw channel temporarily to keep the screw channel free of cement.
12. The milled substructure milled out of the material of choice is cemented onto the TIB abutments and the final restoration constructed and cemented onto this.

Digital workflow by scanning directly without using digital libraries:

Scanning procedures:

1. Attach the TIB abutment to the lab analogue in the master model and screw down with the appropriate laboratory screw and driver.
2. Abutments should be adjusted to the ideal occlusal height.
3. Temporarily cover the screw hole with wax.
4. Scan using usual scan routines.
5. The TIB abutments are anodized gold, and may not need scanning powder or spray in order to scan.
6. Scan using routine scanning procedures.

Designing procedures:

7. The software will guide the user to design the shape of the restoration.

Milling & sintering procedures:

8. Follow steps 10 to 12

TIB Abutment used with Sirona:

Table 2

Implant	TiBase	Software Selection	Scan Body
Ext-Hex	TIB-EX-30	BO 3.4L	L
	TIB-EX-34	BO 3.4L	L
	TIB-EX-40	BO 4.1L	L
	TIB-EX-50	BO 5.0L	L
	TIB-EX-60	NB RS 6.0L	L
Tri-Nex	TIB-EL-35	NB RS 3.5L	L
	TIB-EL-43	NB RS 4.3L	L
	TIB-EL-50	NB RS 5.0L	L
	TIB-EL-60	NB RS 6.0L	L
DC	TIB-DC4	AT OS 3.5/4.0L	L
	TIB-DC5	AT OS 4.5/5.0L	L
Int-Hex	TIB-M	NB RS 4.3L	L
	TIB-Z	B0 5.0L	L

Scanning procedure:

1. Use the corresponding third party Scan body as indicated in Table 2.
2. Choose either the white or grey scanbody depending on the Cerec scanner (refer to Cerec manuals for more detail)
3. Align the guide grooves in the Scan body with the TiB abutment and make sure that it seats flush without any gaps.
4. Select the correct scan body and corresponding TiBase in the software. Refer to Table 2 for correct TiBase selection.
5. Take a scan with your scanner like normal. Ensure that the top of the scan body is completely captured.

Designing procedures:

6. **Note:** The diameter of the TiB abutment must not be reduced. Shortening of the TiB is not permitted.
7. The software will guide the user to design the shape of the restoration.

Milling Procedures:

1. Mill the shape from meso block size L (see the InLab 3D for Abutment User Manual)
2. Carefully follow the instructions and information in the operating instructions for inCoris ZI meso blocks.
3. Send the design files to a milling unit or production facility accepting Sirona designs.

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Final Clinical procedures:

1. Clean and disinfect the restoration as applicable per the restorative material manufacturer's instructions.
   a. For a screw retained units: Place and tighten the restoration screw. Verify the correct seating of the restoration using radiographic imaging. Tighten the restoration using a torque wrench, to the torque value specified for the applicable prosthetic screw. (Refer to Table 1)
   b. For cement retained units: Place and tighten the restoration screw. Verify the correct seating of the substructure/custom post using radiographic imaging. Tighten the substructure/custom post using a torque wrench, to the torque value specified for the applicable prosthetic screw. (Refer to Table 1), Close the screw access holes and cement the final prosthesis in place.

Material

TiB Abutment: Titanium or Titanium alloy (Ti-6AL-4V)
Abutment screws: Titanium alloy Ti-90%, Al-6%, V-4%
Gold alloy Au-61%, Ag-16.5%, Pt-13.5%, Cu -9%

Magnetic Resonance (MR) safety information:

This device has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artefact in the MR environment. The safety of this device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

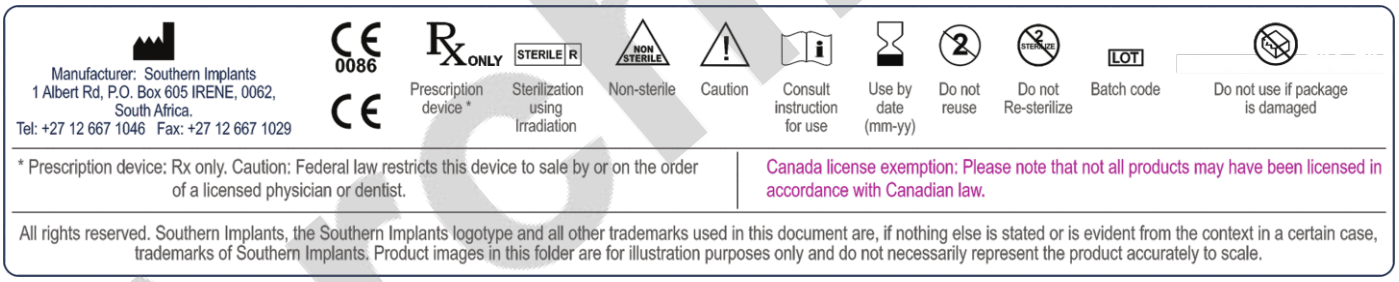
Storage, Cleaning & Sterilization

These abutments are delivered non-sterile and for single use. Final restoration should be cleaned and disinfected, as per restorative material manufacturer's instructions, before intra oral use.
Pre-vacuum sterilization method: Steam sterilise the abutments at 132°C (270°F) at 180-220kPa for 4-7 minutes. Dry for at least 20 minutes in the chamber. Only a FDA approved wrap or pouch for steam sterilization must be used.
The product must be stored in a dry place in the original packaging at room temperature and not exposed to direct sunlight. Incorrect storage may influence device characteristics.

Disposal:

Disposal of the device and its packaging shall follow local regulations and environmental requirements, taking different contamination levels into account.

Symbols & Warnings



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