



Intended use:

Southern Implants Scan Flags are intended to be used during digital impression procedure in order to obtain the exact position and orientation of the respective dental implant or laboratory analogue and transfer this position digitally during CAD/CAM scanning procedures. This aids the CAD/CAM software to align the CAD/CAM restorations to the implant digitally.

Description:

The Scan flags are premanufactured and are available in different connections. The items are to be fitted directly onto implants or indirectly, to the compact conical abutment, or to the laboratory analogue on a dental model. The Scan flags are made from PEEK and is supplied with a screw to secure the Scan flag onto the dental implant or analogue.

NOTE: Southern Implants Scan flags are reusable.

Refer to individual product catalogues for product characteristics and compatible accessories:

Internal Hex (M-Series CAT-2043 & Provata CAT-2060), DC (CAT-2042), Tri-Nex (CAT-2004), IT (CAT-2005), External Hex (CAT-2020).

Table 1.

External hex range		
SF-EX-34	ø3.25mm external hex implant	I-HD-M (1.22 hex)
SF-EX-40	ø4mm external hex implant & MAX-6	
SF-EX-50	ø5mm external hex implant & MAX-7	
SF-EX-60	ø6mm external hex implant & MAX-8	
Tri-Nex range		
SF-EL-35	ø3.5mm Tri-Nex implant	I-UGI-M (Unigrip)
SF-EL-43	ø4.3mm Tri-Nex implant	
SF-EL-50	ø5mm Tri-Nex implant & TRI-MAX7	
SF-EL-60	ø6mm Tri-Nex implant & TRI-MAX8 & 9	
DC- range		
SF-DC3	ø3mm Deep conical implant	I-HD-M (1.22 hex)
SF-DC4	ø4mm Deep conical implant	
SF-DC5	ø5mm Deep conical implant	

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

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Internal hex range		
SF-M	ø3.7 ,4.2, 5mm Internal hex implants / PROVATA & PROMAX 6	I-HD-27-M (1.27 hex)
SF-Z	PROMAX 7,8 & 9	
Internal Octagon range		
SF-IT	ø4.8mm IT implants	I-SCS-M (Torx)
SF-IT6	Ø6mm IT implants & MAXIT	
Abutment level (Compact Conical abutment)		
SF-MC-48	ø4.8mm platform Compact conical abutments	
SF-MC-60	ø6mm platform Compact conical abutments	

NOTE: Refer to product catalogue for more information on Prosthetic screws and instruments.

Indications for use:

Scan flags are indicated for use with intraoral- and desktop scanners as part of planning and design software using 3Shape and Exocad CAD/CAM systems.

A digital impression can be taken at different stages during treatment:

- At time of implant placement – for immediate loading techniques, to deliver a provisional restoration and in certain cases a final restoration on the same day.
- At second stage surgery – after soft tissue healing following second stage surgery procedures.
- At the dental laboratory – After taking impressions digitally for printed models, or taking impressions using conventional method to produce a dental model with laboratory analogues. Attach the Scan flag to the analogue to obtaining the implant position with the aid of a desktop scanner.

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) or PEEK (polyetheretherketone)

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.
- 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.
- Care must be taken that parts are not swallowed during any of the procedures, thus rubber-dam application is recommended when appropriate.
- Regular patient follow-up, and proper oral hygiene must be achieved are essential for favourable long-term results.

Procedure for use:

- Before placing the scan body ensure all items are clean and suitable for intraoral use. If the item is being 're-used', inspect the fitting surface to ensure that there is no damage.
- Attach the matching Scan flag to the dental implant or lab analogue. Check proper fit and hand tighten the screw with the appropriate driver (refer to catalogue or Table 1)
- The patient is scanned using an intraoral scanner, or the laboratory model is scanned using a desktop scanner.
- The Scan flag is removed from the implant or analogue.
- The Scan flag in the digital form is now matched and aligned with the corresponding Scan flag from the library file that was imported into the software. 3Shape and Exocad libraries can be downloaded after registering on www.southernimplants.com.
- The software recognizes the relative position of the Scan flag to the implant or analogue, this allows the software to know where to place the abutment for the design step.

Note: Follow the instructions of the scanner used, and for scan procedures.

Materials:

Scan Flag: Polyetheretherketone (PEEK)
Screw: Titanium Grade 4 (anodized)

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 Scan Flags are delivered non-sterile and are reusable. The Scan flag should be cleaned and disinfected, before intra oral use.

Pre-vacuum sterilization method: Steam sterilise the Scan flag 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.

Scan flags used on an analogue/dental model does not need to be sterilised.

Disposal:

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

Symbols & Warnings

 Manufacturer: Southern Implants 1 Albert Rd, P.O. Box 605 IRENE, 0062, South Africa. Tel: +27 12 667 1046 Fax: +27 12 667 1029	 0086 	 Rx ONLY Prescription device *	 STERILE R Sterilization using Irradiation	 NON-STERILE Non-sterile	 Caution Caution	 Consult instruction for use Consult instruction for use	 Use by date (mm-yy) Use by date (mm-yy)	 Do not reuse Do not reuse	 Do not Re-sterilize Do not Re-sterilize	 LOT Batch code	 Do not use if package is damaged Do not use if package is damaged
* Prescription device: Rx only. Caution: Federal law restricts this device to sale by or on the order of a licensed physician or dentist.						Canada license exemption: Please note that not all products may have been licensed in accordance with Canadian law.					
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For Technical Assistance or additional product literature, please contact Southern Implants.

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