endotine® midfaceB

ENDOTINE Midface B 4.5 Instructions for Use

MICROAIRE® aesthetics

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ENDOTINE Midface™ B 4.5

Part No.	Tine Length	Part Name
CFD-020-0197	4.5 mm	ENDOTINE Midface™ B 4.5
ENDOTINE Midface™ B Instrument Kit, CFD-020-4320		
CFD-020-4302	Drill Bit, 1.25mm	
CFD-020-4200	Tap Tool	
CFD-020-4250	Insertion Tool	
CFD-020-4400	Clipper Tool	
CFD-020-4325	Sterilization Tray	

DESCRIPTION
The ENDOTINE Midface™ B 4.5 consists of bioabsorbable implants: a fixation platform (1A) and two screw anchors (1B) (one spare) (Figure 1). The implants are supplied sterile for single use only. Insertion tools are supplied separately. Installation of the ENDOTINE Midface™ B 4.5 requires the use of Instrument Kit, CFD-020-4320, which is supplied separately.

INDICATIONS
The ENDOTINE Midface™- B 4.5 is indicated for use in subperiosteal midface suspension surgery to fixate the cheek subdermis in an elevated position from the infra-orbital rim or zygoma via an anchoring leash and maintain fixation until healing has occurred.

CONTRAINDICATIONS
1. Situations where internal fixation is otherwise contraindicated (e.g., infection).
2. Patients appearing to have very thin soft tissues of the midface.
3. Any known allergy or foreign-body sensitivities to plastic biomaterial.

PACKAGING, LABELING and STERILIZATION
The ENDOTINE Midface™ B 4.5 implant components are supplied pre-sterilized by gamma irradiation and intended for single use only. Do NOT resterilize these devices. The devices should be accepted only if the factory packaging and labeling arrive intact. Do not use if packaging shows evidence of puncture(s), tampering, water contamination or other damage.

STORAGE INSTRUCTIONS
Store at room temperature (15 to 24°C or 60 to 75°F) in a dry place out of direct sunlight. Do not use beyond the expiration date listed on the outer label. Do not use if the temperature indicator on the carton has turned black; the indicator changes color if the device is subjected to temperatures that could damage it, even if the exposure is of short duration, as might occur during transportation.

INSTRUCTIONS FOR USE
1. Figure 1 shows the implants (fixation platform (1A) and screw anchor (1B)). Note: Two screw anchors are contained in ENDOTINE Midface™ B 4.5. Only one screw anchor is utilized during the procedure, a spare is provided, if needed.
2. Figure 2 shows the installation tools provided in the ENDOTINE Midface B 4.5 Instrument Kit, including the drill bit (2A), tap tool (2B), screw installation tool (2C), and clipper tool (2D). After cleaning and prior to use of the ENDOTINE Midface B 4.5 Instrument Kit, verify that none of the instruments have been damaged. Do not attempt to sharpen or repair the instruments.
3. The midface dissection from the infraorbital approach – with or without additional incisions – is performed using the surgeon's standard technique. The fixation platform should be positioned over the maxillary antrum after elevation (instead of over the zygoma where it is likely to be visible). The dissection should extend to the inferior maxillary area. Care should be taken to avoid injury to the infraorbital nerve.
4. Insert the fixation platform through the infraorbital incision using a clamp or other suitable instrument and position it (in the subperiosteal plane) to the desired location in the midface (Figure 3). Care should be given to avoid damaging the fixation platform and leash while clamping.
5. When comfortable with the position of the fixation platform at the inferior (caudal) recess of the midface dissection, apply moderate digital pressure over the cheek to engage the tines in the midface tissues (Figure 4).
6. Elevate the tissues to the desired position by applying tension to the anchoring leash (Figure 5). If the fixation platform appears prominent on the zygomatic arch, advance the fixation platform more inferiorly (may require additional subperiosteal dissection) and engage and elevate the tissues. Once the desired position is reached, exercise caution with excessive tissue manipulation, endoscopic visualization or drain insertion, as this may dislodge the fixation platform from the tissue.
7. Once optimal midface elevation has been achieved, note or mark the appropriate point on the infraorbital rim or zygomatic bone for screw anchor placement (Figure 6). Shift the leash portion away from the target hole location in order to adequately drill and tap.
8. Drill a hole in the desired position (Figure 7) using the drill bit provided in the Midface B 4.5 Instrument Kit. The drill bit has reached an adequate depth when the stop collar on the bit spins against the bone. Remove any residual loose bone material if present in the hole after drilling.
9. Carefully tap the hole at the same angle used to drill (Figure 8). Stop tapping when the collar lays flat against the bone to avoid stripping the hole.
10. Remove the ENDOTINE Midface B 4.5 screw anchor from the foam packaging using the installation tool provided in the kit by aligning the slot in the end of the installation tool with the tabs on the screw anchor. Engagement shown in Figure 9.
11. Tension the leash such that the tissues are in the optimal position and a leash hole lies over the bone hole.
12. Gently and slowly advance the screw anchor in a clockwise fashion (Figure 9) until it lays flat against the leash. An increase in resistance indicates completion. Any additional torque will break the screw anchor.
13. Trim screw anchor head flush by positioning the clipper tool between the screw head anchor and installation tab (Figure 10). Place your finger over the screw anchor while trimming to constrain the remnant. Discard trimmed portion.
14. Two cuts are required to trim the excess leash. While holding the clipper tool perpendicular to the bone, make each cut between the hole above the screw anchor and the outside edge of the leash (Figure 11).
15. If adjustment or alternative placement of the device is desired at the time of implantation, one may detach the fixation platform under direct vision. An additional drill hole and screw anchor may be required to reposition the device.
16. The patient should be instructed to avoid excessive manipulation or contact with the midface in the initial post-operative period.
17. Should removal of the device be required post-operatively, a small infraorbital incision to release the leash and an oral approach to remove the platform may offer the most straightforward method.

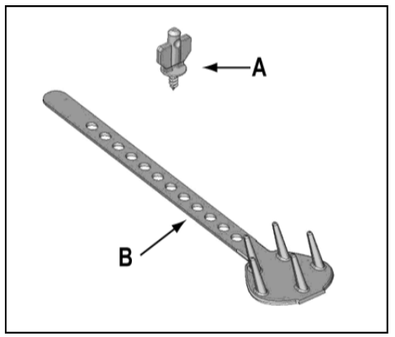
PRECAUTIONS
1. Inform the patient of possible adverse effects, including discomfort, visibility of the device under the skin, and surgical risks (such as nerve injury, facial musculature dysfunction, infection, scarring, device erosion through the skin, asymmetry, loss of suspension/elevation, etc.). The device will likely be palpable prior to absorption. Some devices may require removal prior to full absorption due to discomfort, excessive palpability, infection, allergic reaction or other concerns.
2. Transient local fluid accumulation and/or sinus formation may occur. Aspiration may yield traces of implant material and may result in healing of the sinuses without adverse effects.
3. Atraumatic tines may not penetrate tissues that have been scarred by prior trauma or surgery.

WARNINGS
1. The ENDOTINE Drill Bit provided in the ENDOTINE Midface™ B Instrument Kit must be used to drill the hole.
2. DO NOT RESTERILIZE the ENDOTINE Midface™ B 4.5.
3. Discard open, unused devices.
4. This device is for SINGLE USE ONLY and MUST NEVER BE RE-USED. Resterilization may cause loss of function or failure of the device. Risks of re-use may include patient infection due to lack of sterility.
5. Inspect all components for damage before use. Do not attempt to repair damaged components.
6. DO NOT over tighten the screw anchor during installation.

ADVERSE EFFECTS
Material sensitivity/allergic reactions in patients following surgery should be reported. Implantation of foreign materials in tissues can result in histological reactions.

Caution: Federal Law (USA) restricts this device to sale, distribution, or use by or on the order of a physician.

Figures



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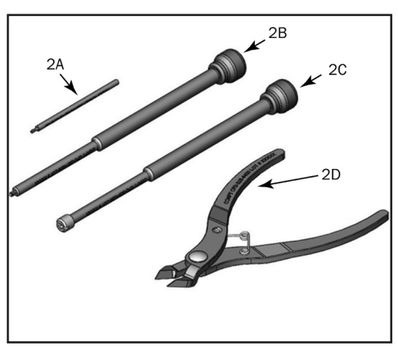

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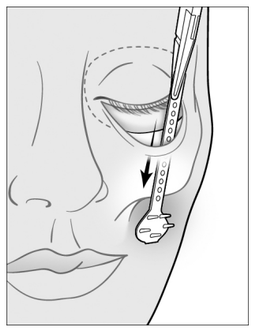

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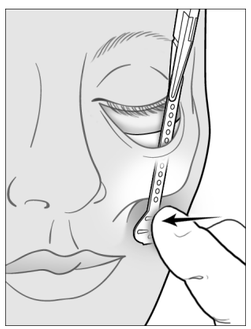

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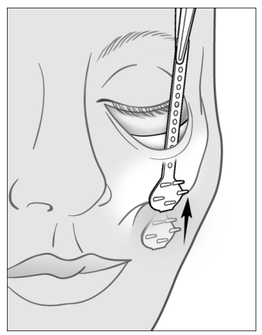

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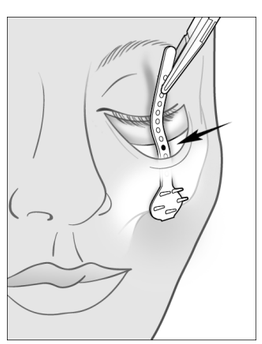

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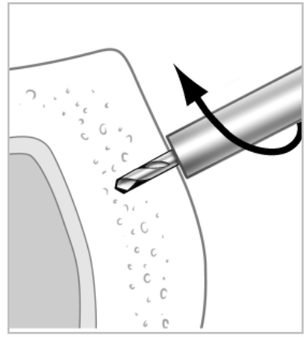

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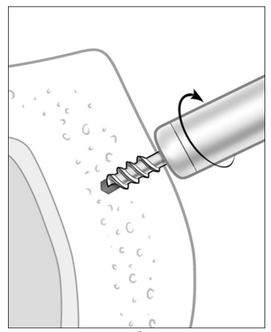

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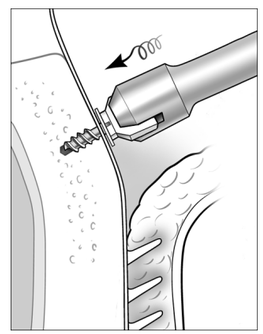
Figures



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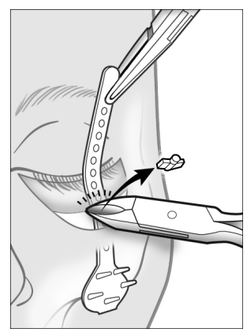

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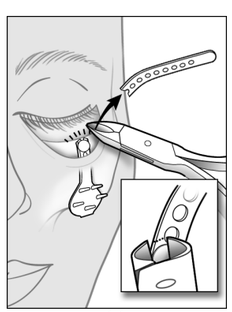

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Symbols

	Caution
	Consult Instructions for Use
	Temperature range
	Use By
Rx ONLY	CAUTION: The United States Federal Law restricts this device to sale by or on the order of a physician.
	Do not reuse
STERILE R	Sterilization using irradiation
REF	Catalogue Number
QUANTITY	Quantity
	Do not use if the product sterilization barrier or its packaging is compromised
	Manufacturer
	Date of Manufacture
LOT	Lot Number

MICROAIRE®

For Surgery. For Life.™

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